24th Annual National Conference on Managing Environmental Quality Systems

8:30 - 12:00 TUESDAY, APRIL 12^{TH} - A.M. Stockholder Meetings

12:00 – 4:30 TUESDAY, APRIL 12TH

Opening Plenary (Salons A-H)

- Opening Address
 - o Reggie Cheatham, Director, OEI Quality Staff, EPA
 - Linda Travers, Principal Deputy Assistant Administrator, OEI, EPA
- Invited Speakers
 - o Tom Huetteman, Deputy Assistant Regional Administrator, EPA Region 9
 - o John Robertus, Executive Officer of San Diego Regional Water Quality Control Board, Region 9
- Keynote Address
 - o Thomas Redman, President, Navesink Consulting Group
- Panel Sessions
- Value of the Data Quality Act—Perspectives from OMB, Industry, and EPA (VDQA)
 - o Nancy Beck, OMB
 - o Jamie Conrad, American Chemistry Council
 - o Reggie Cheatham, Director, OEI Quality Staff, EPA
- Wadeable Streams: Assessing the Quality of the Nation's Streams (WS)
 - o Margo Hunt, Panel Moderator
 - o Mike Shapiro, Deputy Assistant Administrator, Office of Water
 - o Steve Paulsen, Research Biologist, ORD

8:30 - 10:00 WEDNESDAY, APRIL 13TH

Environmental Measures (EM) (Salons A-C) Chair: L. Bradley, EPA

- Data Error Reduction by Automation throughout the Data Workflow Process (A. Gray, EarthSoft, Inc.)
- Analytical Approaches to Meeting New Notification Levels for Organic Contaminants in Calif. (D.Wijekoon, Calif. DHS)
- Streamlining Data Management and Communications for the Former Walker AFB Project (R. Amano, Lab Data Consultants, Inc.)

Quality System Implementation in the Great Lakes Program (QSI-GLP) (Salon D) Chair: M. Cusanelli, EPA

- GLNPO's Quality System Implementation for the New "Great Lakes Legacy Act for Sediment Remediation" (L. Blume, EPA)
- Black Lagoon Quality Plan Approval by GLNPO, MDEQ, ERRS, and USACE (J. Doan, Environmental Quality Management, Inc.)
- Remediation of the Black Lagoon Trenton Channel . . . Postdredging Sampling & Residuals Analysis (J. Schofield, CSC)

Quality Systems Models (QSM) (Salons F-H) Chair: G. Johnson, EPA

 Improving E4 Quality System Effectiveness by Using ISO 9001: 2000 Process Controls (C. Hedin, Shaw Environmental)

Applications of Novel Techniques to Environmental Problems (ANTEP) (Salon E) Chair: B. Nussbaum, EPA

- On Some Applications of Ranked Set Sampling (B. Sinha, University of Maryland)
- Combining Data from Many Sources to Establish Chromium Emission Standards (N. Neerchal, University of Maryland)
- Estimating Error Rates in EPA Databases for Auditing Purposes (H. Lacayo, Jr., EPA)
- Spatial Population Partitioning Using Voronoi Diagrams For Environmental Data Analysis (A. Singh, UNLV)

Ambient Air Session I (Sierra 5&6) Chair: M.Papp, EPA

- Changes and Improvements in the Ambient Air Quality Monitoring Program Quality System (M. Papp, EPA)
- Guidance for a New Era of Ambient Air Monitoring (A. Kelley, Hamilton County DES)
- Environmental Monitoring QA in Indian Country (M. Ronca-Battista, Northern Arizona University)
- Scalable QAPP IT Solution for Air Monitoring Programs (C. Drouin, Lake Environmental Software)

10:30 - 12:00 WEDNESDAY, APRIL 13TH

Environmental Laboratory Quality Systems (ELQS) (Salons A-C) Chair: L. Bradley, EPA

- A Harmonized National Accreditation Standard: The Next Step for INELA Field Activities (D. Thomas, Professional Service Industries, Inc.)
- Development of a Comprehensive Quality Standard for Environmental Laboratory Accreditation (J. Parr, INELA)
- Advanced Tracking of Laboratory PT Performance and Certification Status with Integrated Electronic NELAC-Style Auditing Software (T. Fitzpatrick, Lab Data Consultants, Inc.)

Performance Metrics (PM) (Salon D) Chair: L. Doucet, EPA

- Formulating Quality Management Metrics for a State Program in an Environmental Performance Partnership Agreement (P. Mundy, EPA)
- How Good Is "How Good Is?" (Measuring QA) (M. Kantz, EPA)
- Performance-Based Management (J. Santillan, US Air Force)

Quality Assurance Plan Guidance Initiatives (QAPGI) (Salons F-H) Chair: A. Batterman, EPA

- A CD-ROM Based OAPP Preparation Tool for Tribes (D. Taylor, EPA)
- Military Munitions Response Program Quality Plans (J. Sikes, U.S. Army)

Ask a Statistician: Panel Discussion (Salon E) Moderator: B. Nussbaum, EPA Panelists:

- Mike Flynn, Director, Office of Information Analysis and Access, OEI, EPA
- Reggie Cheatham, Director, Quality Staff, OEI, EPA
- Tom Curran, Chief Information Officer, OAQPS, EPA
- Diane Harris, Quality Office, Region 7, EPA
- Bill Hunt, Visiting Senior Scientist, North Carolina State University (NCSU)
- Rick Linthurst, OIG, EPA

Ambient Air Session II (Sierra 5&6) Chair: M. Papp, EPA

- National Air Toxics QA System and Results of the QA Assessment (D. Mikel, EPA)
- Technical System Audits (TSAs) and Instrument Performance Audits (IPAs) of the National Air Toxics Trends Stations (NATTS) and Supporting Laboratories (S. Stetzer Biddle, Battelle)
- Interlaboratory Comparison of Ambient Air Samples (C. Pearson, CARB)
- Developing Criteria for Equivalency Status for Continuous PM2.5 Samplers (B. Coutant, Battelle)

1:00 - 2:30 WEDNESDAY, APRIL 13^{TH}

Environmental Laboratory Quality (ELQ) (Salons A-C) Chair: L. Doucet, EPA

- Environmental Laboratory Quality Systems: Data Integrity Model and Systematic Procedures (R. DiRienzo, DataChem Laboratories, Inc.)
- The Interrelationship of Proficiency Testing, Interlaboratory Statistics and Lab QA Programs (T. Coyner, Analytical Products Group, Inc.)
- EPA FIFRA Laboratory Challenges and Solutions to Building a Quality System in Compliance with International Laboratory Quality Standard ISO 17025 (A. Ferdig, Mich. Dept. of Agriculture)

Performance—Quality Systems Implementation (P-QSI) (Salon D) Chair: A. Belle, EPA

• Implementing and Assessing Quality Systems for State, Tribal, and Local Agencies (K. Bolger, D. Johnson, L. Blume, EPA)

1:00 – 2:30 WEDNESDAY, APRIL 13TH (continued)

 $\textbf{Quality Initiatives in the EPA Office of Environmental Information (QI-OEI)} \ (\textbf{Salons F-H}) \ \textit{Chair: J. Worthington, EPA}$

- Next Generation Data Quality Automation in EPA Data Marts (P. Magrogan, Lockheed)
- The Design and Implementation of a Quality System for IT Products and Services (J. Scalera, EPA)
- Data Quality is in the Eyes of the Users: EPA's Locational Data Improvement Efforts (P. Garvey, EPA)

A Win-Win-Win Partnership for Solving Environmental Problems (W3PSEP) (Salon E) Co-Chairs: W. Hunt, Jr. and K. Weems, NCSU

- Overview of Environmental Statistics Courses at NCSU (B. Hunt, NCSU Statistics Dept.)
- Overview of the Environmental Statistics Program at Spelman College (N. Shah, Spelman)
- Student presentations: H. Ferguson and C. Smith of Spelman College; C. Pitts, B. Stines and J. White of NCSU

Ambient Air Session III (Sierra 5&6) Chair: M. Papp, EPA

- Trace Gas Monitoring for Support of the National Air Monitoring Strategy (D. Mikel, EPA)
- Comparison of the Proposed Versus Current Approach to Estimate Precision and Bias for Gaseous Automated Methods for the Ambient Air Monitoring Program (L. Camalier, EPA)
- Introduction to the IMPROVE Program's New Interactive Web-based Data Validation Tools (L. DeBell, Colorado State University)
- The Role of QA in Determination of Effects of Shipping Procedures for PM2.5 Speciation Filters (D. Crumpler, EPA)

3:00 – 4:30 WEDNESDAY, APRIL 13TH

Topics in Environmental Data Operations (TEDO) (Salons A-C) Chair: M. Kantz, EPA

- Ethics in Environmental Operations: It's More Than Just Lab Data (A. Rosecrance, Laboratory Data Consultants, Inc.)
- QA/QC of a Project Involving Cooperative Agreements, IAGs, Agency Staff and Contracts to Conduct the Research (A. Batterman, EPA)
- Dealing with Fishy Data: A Look at Quality Management for the Great Lakes Fish Monitoring Program (E. Murphy, EPA)

Quality System Development (QSD) (Salon D) Chair: A. Belle, EPA

- Development of a QA Program for the State of California (B. van Buuren, Van Buuren Consulting, LLC)
- Integrating EPA Quality System Requirements with Program Office Needs for a Practical Approach to Assuring Adequate Data Quality to Support Decision Making (K. Boynton, EPA)
- Introducing Quality System Changes in Large Established Organizations (H. Ferguson, EPA)

Auditor Competence (AC) (Salons F-H) Chair: K. Orr, EPA

• Determining the Competence of Auditors (G. Johnson, EPA)

To Detect or Not Detect—What Is the Problem? (TDND) (Salon E) Chair: J. Warren, EPA

- A Bayesian Approach to Measurement Detection Limits (B. Venner)
- The Problem of Statistical Analysis with Nondetects Present (D. Helsel, USGS)
- Handling Nondetects Using Survival Anal.(D. Helsel, USGS)
- Assessing the Risk associated with Mercury: Using ReVA's Webtool to Compare Data, Assumptions and Models (E. Smith, EPA)

Ambient Air Session IV (Sierra 5&6) Chair: M. Papp, EPA

- Status and Changes in EPA Infrastructure for Bias Traceability to NIST (M. Shanis, EPA)
- Using the TTP Laboratory at Sites with Higher Sample Flow Demands (A. Teitz, EPA)

5:00 – 6:00 PM WEDNESDAY, APRIL 13TH

EPA SAS Users Group Meeting Contact: Ann Pitchford, EPA

8:30 - 10:00 THURSDAY, APRIL 14^{TH}

Evaluating Environmental Data Quality (EEDQ) (Salons A-C) Chair: M. Kantz, EPA

- QA Documentation to Support the Collection of Secondary Data (J. O'Donnell, Tetra Tech, Inc.)
- Staged Electronic Data Deliverable: Overview and Status (A. Mudambi, EPA)
- Automated Metadata Reports for Geo-Spatial Analyses (R. Booher, INDUS Corporation)

Satellite Imagery QA (SI-QA) (Salon D) Chair: M. Cusanelli, EPA

• Satellite Imagery QA Concerns (G. Brilis and R. Lunetta, EPA)

Information Quality Perspectives (IQP) (Salons F-H) Chair: J. Worthington, EPA

- A Body of Knowledge for Information and Data Quality (J. Worthington, L. Romero Cedeno, EPA)
- Information as an Environmental Technology Approaching Quality from a Different Angle (K. Hull, Neptune and Co.)

To Detect or Not Detect—What Is the Answer? (TDND) (Salon E) Chair: A. Pitchford, EPA, Co-Chair: W. Puckett, EPA

- Using Small Area Analysis Statistics to Estimate Asthma Prevalence in Census Tracts from the National Health Interview Survey (T. Brody, EPA)
- Logistical Regression and QLIM Using SAS Software (J. Bander, SAS)
- Bayesian Estimation of the Mean in the Presence of Nondetects (A. Khago, University of Nevada)

Ambient Air Workgroup Meeting (Sierra 5&6) Contact: Mike Papp, EPA

NOTE: This is an all-day, closed meeting.

10:30 - 12:00 THURSDAY, APRIL 14TH

Environmental Data Quality (EDQ) (Salons A-C) Chair: V. Holloman, EPA

- Assessing Environmental Data Using External Calibration Procedures (Y. Yang, CSC)
- Groundwater Well Design Affects Data Representativeness: A Case Study on Organotins (E. Popek, Weston Solutions)

Information Quality and Policy Frameworks (IQPF) (Salons F-H) Chair: L. Doucet, EPA

- Modeling Quality Management System Practices to an Organization's Performance Measures (J. Worthington, L. Romero Cedeño, EPA)
- Development of a QAPP for Agency's Portal (K. Orr, EPA)
- Discussion of Drivers and Emerging Issues, Including IT, That May Result in Revisions to EPA's Quality Order and Manual (R. Shafer, EPA)

Office of Water; Current Initiatives (OW) (Salon D) Chair: D. Sims, EPA

- Whole Effluent Toxicity--The Role of QA in Litigation (M. Kelly, EPA, H. McCarty, CSC)
- Review of Data from Method Validation Studies: Ensuring Results Are Useful Without Putting the Cart Before the Horse (W. Telliard, EPA, H. McCarty, CSC)
- Detection and Quantitation Concepts: Where Are We Now? (Telliard, Kelly, and McCarty)

Sampling Inside, Outside, and Under (SIOU) (Salon E) Chair: J. Warren, EPA

- VSP Software: Designs and Data Analyses for Sampling Contaminated Buildings (B. Pulsipher, J. Wilson, Pacific Northwest National Laboratory, R. O. Gilbert)
- Incorporating Statistical Analysis for Site Assessment into a Geographic Information System (D. Reichhardt, MSE Technology Applications, Inc.)
- The OPP's Pesticide Data Program Environmental Indicator Project (P. Villanueva, EPA)

1:00 - 2:30 THURSDAY, APRIL 14TH

Information Management (Salons A-C) Chair: C. Thoma, EPA

• Achieve Information Management Objectives by Building and Implementing a Data Quality Strategy (F. Dravis, Firstlogic)

UFP Implementation (Salon D) Chair: D. Sims, EPA

- Implementing the Products of the Intergovernmental DQ Task Force: The UFP QAPP (R. Runyon, M. Carter, EPA)
- Measuring Performance: The UFP QAPP Manual (M. Carter, EPA, C. Rastatter, VERSAR)

Quality Systems Guidance and Training Developments (QSG) (Salons F-H) Chair: M. Kantz, EPA

- A Sampling and Analysis Plan Guidance for Wetlands Projects (D. Taylor, EPA)
- My Top Ten List of Important Things I Do as an EPA QA and Records Manager (T. Hughes, EPA)
- I'm Here---I'm Free----Use Me! Use Me!—Secondary Use of Data in Your Quality System (M. Kantz, EPA)

Innovative Environmental Analyses (IEA) (Salon E) Chair: M. Conomos, EPA

- Evaluation of Replication Methods between NHANES 1999-2000 and NHANES 2001-2002 (H. Allender, EPA)
- Assessment of the Relative Importance of the CrEAM Model's Metrics (A. Lubin, L. Lehrman, and M. White, EPA)
- Statistical Evaluation Plans for Compliance Monitoring Programs (R. Ellgas, Shaw Environmental, Inc.; J. Shaw, EMCON/OWT, Inc.)

Data Integrity Model and Systematic Procedures Robert P. Di Rienzo Vice President Quality Assurance / Information Technology DataChem Laboratories, Inc.

Abstract

A laboratory must have a quality system that ensures that 1) the data are of known and documented quality and 2) the data can be used for the intended purpose. The data integrity model and systematic procedures described in this quality system ensure that laboratory data produced are of the highest integrity and meet the criteria as stated above. This policy must incorporate the code of conduct or shared values set by the organization's long range planning. All businesses must have a systematic planning process that defines the road map for the organization. In other words, as an organization we need to ask ourselves, why are we here?

A policy on data integrity and ethics, initiated at the top of an organization, leads to ethical behaviors. The data integrity and ethics policy requires support by standard operating procedures, employee training, internal audit and reporting systems and ultimately by all individuals that make up the organization. Procedures must encompass all analytical processes and primarily address: documentation, peer review, nonconformances, internal audits, client communications and training.

Documentation must address the use of notebooks and logbooks, manual integration, and standard traceability procedures to ensure that the data generated are of known and documented quality. The peer review procedures have to address proper review of all analytical data, as well as support continuous quality improvement of laboratory processes. A non-conformance procedure must be a no-fault procedure that documents any corrective action taken, includes a technical review of corrective actions, communicates to the client, and identifies systematic problems in the laboratory. Internal auditing must function independently from laboratory operations to assess compliance with laboratory quality systems or methods or procedures, review raw data documentation, and most of all lead the laboratory toward continuous quality improvement.

Well defined client communication procedures help to document the purpose of the analytical work to be performed and requirements for compliance with project related quality assurance and sampling plans. Client communication procedures promote the ideology that laboratory staff and the client work as partners to produce data useful for the intended purpose. Finally, and most important is the training program and training documentation to ensure that policies and procedures are useful, understood, and utilized by all employees.

Introduction

Data Integrity and Ethics policies and procedures are essential business practices that promote the generation of data of known and documented quality. Organizations must have leaders that use systematic planning to define the vision and shared values for the organization. Employees of any organization need to know why they are doing what they do. This business model design relates ethical behavior to values and requires that employees of the organization share a common vision of success. Policies and procedures which are consistent with company vision and values ensure data integrity and ethical conduct.

Leadership and Ethics

The best organizations are able to communicate company vision and shared values to elevate those that work on its behalf. The Data Integrity and Ethics policies must be consistent with the vision and shared values of the organization so that the individuals understand the business and their role in ethical behavior. Effective leadership is responsible for planning and communicating an understanding of the organization's purpose, business, and values to all employees. Strategic Planning is one process by which the purpose, business, and values of an organization can be promoted to gain increased levels of employee commitment.

Leadership and Ethics are mutually advantageous as shown in Figure 1. The vision and shared values represent the core priorities in the organization's culture and ethical conduct. Discrepancies between core priorities and Data Integrity and Ethics systems indicate a potential for poor decision making and unethical behaviors.

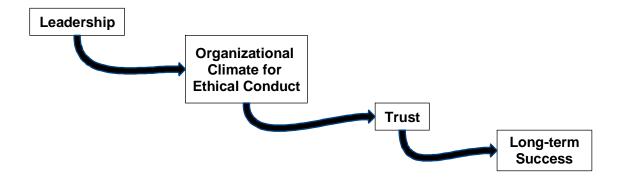


Figure 1. A Framework for Leadership and Ethics

The organization's leaders must communicate the vision and shared values to create a climate for ethical conduct. Trust is placed in employees to implement data integrity policies and procedures which lead to the long-term success of the organization.

"There's nothing more demoralizing than a leader who can't clearly articulate why we're doing what we're doing."

James Kouzes and Barry Posner "The Leadership Challenge"

Chesire Puss, asked Alice, "Would you tell me, please, which way I ought to go from here?"

- "That depends a good deal on where you want to go," said the cat.
- "I don't much care where," said Alice.
- "Then it doesn't mater which way you go," said the cat.

Lewis Carrol, "Alice's Adventure in Wonderland"

Vision

We will be recognized by our peers and clients as the premier analytical chemistry laboratory in the U.S.

Quality Data on Time

Vision is defined as the guiding image of success for the organization. This image of success inspires and motivates people to work together. Leaders must be open and clear on vision and enlist support from all employees in "how to" plans.

Shared Values

INTEGRITY – We will be honest and above board in all dealings with clients, fellow employees, and the company.

QUALITY – We will strive to achieve excellence in all services provided and will work continually to show improvement in all our endeavors.

EMPLOYEE EMPOWERMENT – We will create and maintain an employment environment that provides employees opportunities to grow, excel, and achieve upward mobility. Employees will have authority that is commensurate with their responsibilities.

CUSTOMER SATISFACTION – We will meet customer expectations and needs to the best of our abilities.

PROGRESS/INNOVATION – We will expend the resources necessary to ensure that we stay on the leading edge of technology. We will continually work to identify and implement new ideas and ways of doing things for the betterment of the company.

ORGANIZATIONAL HEALTH – We will provide a safe and secure workplace for employees.

PROTECTION OF THE ENVIRONMENT – We will maintain an awareness of environmental issues and ensure that the Company complies with all relevant environmental statutes and regulations.

SHARING COMMON GOALS – We will work together as a team to achieve established corporate goals. We will communicate these goals to all employees and do everything in our power to see that those goals are met.

RECEPTIVENESS – We will create and maintain a corporate culture that encourages receptivity to employees' ideas and feelings. Management will listen to suggestions for improvement with an open mind.

PERSONAL GROWTH – We will work together to ensure individual and corporate success while maintaining an awareness of individual challenges and helping employees to resolve difficult issues.

Organizations need a sound set of beliefs to achieve success and to serve as a premise for all policies, procedures, and actions. Shared values are used every day by employees to make decisions. The values we have will determine respect for individuals, how customer service is applied, and the overall excellence of the organization. These values are paramount to ensuring a solid data integrity and ethics system. Webster's definition of ethics is "a set of moral principles or values."

The Data Integrity and Ethics Policy must be consistent with the vision and shared values of the organization. The policy must stress the importance of following all standard operating procedures as well as the importance of documenting deviations from procedures, non-conforming events, or any corrective actions that may accompany analytical data. This policy must establish the responsibilities for each level of authority and address disciplinary actions for unethical conduct. The policy should address confidential reporting and notification procedures and identify the supporting procedures that encompass the data integrity system.

"It's not enough that we do our best; sometimes we have to do what's required."

Sir Winston Churchill

NELAC Requirements

Guidance for a quality system for laboratories that addresses data integrity and ethics is given in NELAC Chapter 5 section 5.1.7. The NELAC standard further defines requirements as Management Responsibilities, Training, and Control and Documentation. The following summarizes the NELAC requirements.

Management Responsibilities: (NELAC 2003 section 5.4.2.6)

Data Integrity Policies and Procedures must be defined in the Quality Manual.

The four required elements within the data integrity system are:

- > Training
- > Signed data integrity documentation for all employees
- ➤ In-depth periodic monitoring of data integrity
- > Data integrity procedure documentation

A reporting mechanism that is confidential, receptive and has procedures that require laboratory management to be informed of instances of ethical concern

Training: (NELAC 2003 section 5.5.2.7)

All new employees require initial orientation training on data integrity policies and procedures as well as an annual refresher for all employees.

The topics covered during training sessions must be documented and include the following:

- > Organization's mission
- ➤ Need for honesty and full disclosure
- ➤ How and when to report data integrity issues
- > Documentation and recordkeeping procedures
- > Data integrity policies and procedures
- ➤ Discussion of the required elements of the data integrity system
- > Disciplinary actions
- > Training documentation
- > Examples of improper behaviors
- ➤ Importance of written narration with respect to the analytical results

Control and Documentation: (NELAC 2003 section 5.4.1.5)

As part of internal audits the laboratory must ensure that review with respect to any inappropriate actions or vulnerabilities is conducted. Potential issues must be handled confidentially until follow-up, fully investigated, appropriate actions are completed, and issues are resolved. The documentation of these findings must include any disciplinary actions, corrective actions, and any notification to clients. These findings must be retained for five years.

"Good people do not need laws to tell them to act responsibly, while bad people will find a way around the laws."

Plato

Systematic Procedures

Procedures designed by the laboratory must be consistent with the Data Integrity and Ethics Policy, must meet the required regulation, and be consistent with common business practices concerning ethical behaviors. The supporting procedures must reflect

current practices and document the data integrity system. The following topics should be addressed when designing supporting procedures for the data integrity system.

- > Employee training and documentation
- > Internal auditing and reporting
- > Documentation of analytical results including manual integration
- > Peer review of analytical results
- ➤ Non-conformances and corrective actions
- ➤ Client communication procedures

For the procedures listed above, the following summaries provide the objectives and responsibilities for each procedure.

Employee Training and Documentation

Objectives

- > To ensure employees receive appropriate training
- > To provide new employee orientation training consisting of safety, computer systems, and quality assurance, as well as Data Integrity and Ethics
- > To complete initial analytical training and demonstration of capability
- ➤ To assign SOPs for which analytical personnel are required to have training and to establish proficiency for performance of analysis, reporting, and documentation
- To assign SOPs which are required for all employees
- > To ensure documentation of analyst experience and training

Responsibilities

Technical Manager, Project Manager or Supervisor:

- > Direct activities for initial and on-going employee training
- Assign reading of individual SOPs or manuals addressing the procedures for which the individual employee is responsible
- Assign trainers to train individuals for each specific procedure they perform and ensure that individuals receive documented training in a procedure before they are allowed to perform the procedure without direct supervision
- Measure the performance proficiency of the trainee
- Ensure that employees have safety training related to hazards posed by specific duties and operations
- ➤ Certify all analysts to perform specific procedures

All Employees:

- > Document understanding and usage of new or revised SOPs
- > Become certified for all analyses performed
- ➤ Maintain and update official QA copy of his/her training record by supplying copies of pertinent records to QA personnel

Quality Assurance:

- ➤ Maintain copies of employee training records
- ➤ Maintain documentation of analyst proficiency
- Audit records to ensure compliance with applicable procedures and regulations

Internal Auditing and Reporting

Objectives

- To develop procedures for examining and verifying laboratory operations
- ➤ To conduct annual audits of all analytical procedures, activities, and documentation to ensure compliance with written procedures
- ➤ To undertake internal audits of specific procedures or systems when requested by an analyst or manager
- > To perform internal audits announced or unannounced
- To create checklists for auditors for conducting routine internal audits
- ➤ To use applicable regulations (eg. NELAC or AIHA) for all quality systems audits
- To facilitate upper management review of laboratory operations

Responsibilities

Technical Manager, Project Manager or Supervisor:

- > Respond to audit findings with appropriate corrective action
- > Ensure implementation of corrective actions
- Respond to audit reports in a timely manner
- > Prepare audit responses and submit to the Quality Assurance Management

All Employees:

- > Remain open and responsive to audit questions
- > Respond to requests for information in a timely manner
- Understand and complete corrective actions

Quality Assurance:

- > Review audit reports for appropriateness
- > Schedule audits to be conducted
- Ensure all forms and documents used in internal audit become part of the audit report records
- ➤ Address final internal audit report to the Laboratory Director
- Examine and verify laboratory operations and documentation
- > Report findings in a timely manner
- ➤ Have experience or training and an understanding of Quality Assurance Plans and applicable QA/QC procedures
- ➤ Read and understand applicable quality system regulations

Documentation of Analytical Results Including Manual Integration

Objectives

- > To document procedures applicable to all notebooks for all aspects of sample preparation and analysis as well as laboratory support functions such as sample receipt and long-term sample storage
- To document procedures for all solution and reagent preparation and labeling
- > To document procedures for all analytical standards, including traceability requirements
- To design proper narration for all analytical results
- ➤ To create manual integration procedures including appropriateness and techniques for proper integration
- > To develop procedures for changes or amendments to analytical data

Responsibilities

Technical Manager, Project Manager or Supervisor:

- Ensure that necessary, pertinent information is recorded
- > Review narratives concerning analytical data
- > Implement logbook and notebook formats that include all required information
- ➤ Ensure compliance with Standard Operating Procedures
- ➤ Ensure all changes to documents and reports are properly documented in accordance with established procedures

All Employees:

- Ensure that necessary and pertinent information for analytical narration is recorded
- ➤ Enter required information in pertinent notebooks and logbooks in accordance with procedures
- ➤ Review notebooks and logbooks in accordance with procedures
- > Perform proper manual integration and documentation requirements

Quality Assurance:

Audit records to ensure compliance with applicable procedures and regulations

Peer Review of Analytical Results

Objectives

- To develop a peer review process that will be used to verify the accuracy of data generated by the laboratory
- To acquire experience and training required for Peer Review
- > To design procedures or checklists used to review all data prior to submission of the final report

- To implement procedures for review of reports with respect to client project requirements, data package requirements and applicable regulations
- ➤ To make specific review procedures available to all operational sections
- To develop procedure for minimum and multiple review levels
- ➤ To ensure continuous quality improvement by correcting errors directly at the source

Responsibilities

Technical Manager, Project Manager or Supervisor:

- ➤ Provide appropriate resources and training of peer reviewers
- > Ensure that errors are corrected at the source

All Employees:

- Review data in accordance with established procedures
- ➤ Certify compliance with procedures by signing report
- ➤ Ensure that appropriate evaluation criteria are used as defined by the project protocol
- Ensure that errors are corrected at the source

Quality Assurance:

- Evaluate data packages for compliance with project requirements
- ➤ Evaluate non-conformance situations for peer review compliance

Non-conformances and Corrective Actions

Objectives

- To provide procedures which are easy to perform and do not carry any weight with respect to employee performance or disciplinary actions
- To define nonconformance, corrective actions, and root cause analysis
 - o A nonconformance is a situation that does not conform to the requirements of an SOP, method, project, contract, QA plan, or regulation
 - o A corrective action is a proposed solution to the non-conformance that may or may not require root cause analysis
 - O Root cause analysis occurs when a systematic non-conformance which consumes resources and tends to happen repeatedly. The laboratory must do root cause analysis to find out what is really causing this situation to occur and remove it so the situation does not occur again, thus eliminating the need to continue to deal with the symptoms
- ➤ To develop procedures that identify, document, evaluate, and correct nonconformance in analytical operations
- ➤ To design and implement procedures that evaluate root cause, assign specific corrective actions, and initiate follow-up action to verify that corrective actions are effective and complete
- ➤ To identify corrective action measures

> To provide procedures to document and resolve client requests to review or revise data

Responsibilities

Technical Manager, Project Manager or Supervisor:

- ➤ Determine whether corrective action is necessary when a nonconformance has been identified
- Review the QC data items pertaining to analytical data, the proposed corrective action, and implement the corrective action
- ➤ Notify the client of any documented nonconformance and serve as a liaison between the client and the laboratory
- > Initiate this procedure at the request of a client
- ➤ Make determinations if non-conforming situations are systematic and require additional corrective action or formal root cause analysis

All Employees:

- ➤ Immediately initiate NC/CAR procedures when a non-conforming situation is detected or a client has requested a review of reported data
- > Ensure that all appropriate personnel are informed of the nonconformance and/or corrective action
- > Review the QC data items and suggest appropriate corrective action

Quality Assurance:

- ➤ Review completed NC/CARs for appropriateness and corrective actions
- ➤ Make determinations if non-conforming situations are systematic and require additional corrective action or formal root cause analysis
- Review corrective actions during audits for implementation and compliance

Client Communication Procedures

Objectives

- To describe the fundamental components of communication
- To establish successful relationships with clients through effective communication
- ➤ To assure problems are identified, documented and resolved through communication with the client
- To define projects in sufficient detail to ensure client requirements are met, document quality of analytical data and that the data is appropriate for its intended use
- > To outline procedures to ensure review of contracts and tenders including a review of capabilities and resources needed to complete projects
- > To effectively communicate project needs to laboratory operations
- > To respond to client concerns
- > To effectively manage on-going projects within the laboratory

Responsibilities

Technical Manager, Project Manager or Supervisor:

- > Document all project communication with the client.
- > Document all instructions to the laboratory for successful project completion.
- Resolve problems with clients and provide documentation applicable to resolution

All Employees:

> Follow all client instructions as provided by Project Managers to produce project compliant analytical data

Quality Assurance:

- Review compliance with procedures for proper client communication documentation
- Respond to client requests for method or package audits

Conclusions

Leaders inspire critical vision and values to the organization. Data integrity and ethics, supported by vision and values, play an immediate role in both the short-term and long-term success of an organization. Even though variations in ethical conduct are influenced greatly by the managers of an organization, the values included in policies on data integrity and ethics influence all ethical decision making. Well defined procedures and responsibilities for laboratory processes, that support the data integrity and ethics system, are a vital factor in making ethical choices.

"There is no such thing as a minor lapse of integrity"

Tom Peters

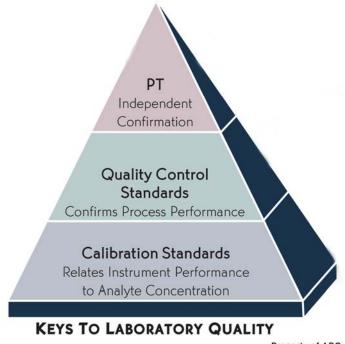
The Interrelationship of Proficiency Testing, Interlaboratory Statistics and Laboratory Quality Assurance Programs

Thomas V. Coyner Analytical Products Group, Inc.

The fundamental concepts of Quality Control and Quality Assurance are understood by most laboratory analysts; however, many times they struggle with the actual implementation of a Quality Control system to support the technical defensibility of their data. How do matrix spikes, matrix duplicates, laboratory control standards, and calibration fit together to give you defensible results? Most approved environmental methods have an extensive Quality Control section, but the pieces still do not seem to fit.

It is important to realize that environmental analysis is essentially a two-step series of processes. The basic process considers the sample as the input and sample data as the outline. In this sense, the matrix spike and matrix duplicate are quality control on this sample processing system. The second process is the test method itself, and the laboratory quality control standard should monitor this process.

It is the second process, the test method, and it's Quality Control which are the focus of this discussion. Analytical Products Group, Inc. has developed a simple graphic to demonstrate the interrelation of calibration, quality control standards, and proficiency testing (PT).



Property of APG

The relative size and location of each of the elements in the triangle correspond to the importance and function of each element. The most important element in an analytical system is the calibration. Without a sound calibration, there is nothing you can do to improve the quality of the data. Therefore, great care should be given to verifying the accuracy and linearity of the calibration. It must be noted that the standard referred to as the Continuing Calibration Verification (CCV) standard is not a verification sample. It simply records the "drift" in the method calibration over time. Calibration is also the area where you can see the greatest return on investment. A simple change from undocumented standards to NIST traceable standards will go a long way to ensure data defensibility. Unfortunately, virtually all of the organic standards commercially available lack traceability, so it is critically important to verify organic calibrations against a second source, or better yet, a quality control standard with documented performance.

Many EPA methods include a requirement for a laboratory control standard (LCS). The requirement usually is that the standard contains every analyte in the method, be prepared within the calibration range, be run on a set frequency, and be processed as a sample. The purposes of the LCS are to verify the calibration and to establish working quality control limits for the laboratory. The most important of these requirements is that the LCS be run as a sample, and therefore, go through the entire sample preparation process. Conversely, the requirement to contain all of the analytes is less important but forces the laboratory to prepare the LCS from a calibration standard. Unfortunately, an LCS prepared from a calibration standard only has a documented true value. Opposed to this approach, a Quality Control Standard certified in an interlaboratory PT program contains more useful information but typically lacks all of the analytes in the method.

An interlaboratory certified Quality Control Standard has a certified true value much like a calibration material. However, because it has been certified in an interlaboratory program where it was run as a sample, it has established typical laboratory performance ranges established in the study. This gives a laboratory a verification of its internal quality control limits and avoids failures on PT samples. Since most inorganic Quality Control Standards are also NIST traceable, this would make every analytical run a NIST traceable analysis which provides better verification of the calibration and provides greater value to the data user.

Similarly, an interlaboratory certified Quality Control Standard is an ideal tool for method validation or analyst training verification. In both cases, the standard has sufficient documentation to support the data needs of these analyses. Finally, this type of Quality Control Standard is also an excellent tool to verify the effectiveness of a corrective action because successful performance within the defined laboratory performance range is a demonstration of performance comparable to other laboratories running the same sample.

Proficiency Testing for Quality Improvement:

Proficiency testing programs, sometimes referred to as round-robins or interlaboratory programs, have been used for many years and for various purposes. ASTM and AOAC use these programs to verify and document the performance of new methods. For the past twenty years, USEPA has used proficiency testing to monitor the quality of environmental laboratory data through the WP, WS, and DMRQA PT programs. During the 1990s, the International Standard Organization (ISO) recognized the need to develop a uniform protocol for proficiency testing of all analytical laboratories and established a workgroup for this purpose. The final Harmonized Protocol for the Proficiency Testing of Analytical Laboratories is generally accepted as the international guide for the operation of these programs. The Protocol recognizes the utility of proficiency testing programs as a quality improvement tool as well as a means of establishing and monitoring laboratory performance.

However, both USEPA and, more recently, the National Environmental Laboratory Accreditation Program (NELAP) have chosen to focus their PT programs on laboratory control rather than monitoring or quality improvement. They both do this by requiring that laboratories be evaluated based upon acceptance limits calculated from the Assigned Value of the samples and previous PT studies rather than using the data developed in the actual study under evaluation. By using this evaluation scheme, both groups lose the important information gathered by the study, fail to understand changes in laboratory performance, lose valuable method performance data, and develop unrealistic performance expectations for their methods and the laboratories that run them.

Proficiency testing programs are fundamentally a peer review process. They allow the comparison of laboratories on the same samples, run at the same time. However, the idea of a peer review process requires that all laboratories be treated fairly and equally. Therefore, the samples must be properly prepared and evaluated for homogeneity prior to the study and for stability after the study. Similarly, the samples must be designed to "challenge" the method; that is, they must not be too easy or be so difficult that they cannot be successfully run by the appropriate methods. Given these precautions, a PT program can provide valuable information for both the laboratory and the program operator.

What can be gained from a PT program is dependent upon the final data analysis. If the goal of the program is to evaluate the performance of the laboratories against the True Value of the samples, then percent recovery or En value, which measure deviation from the reference value, can be used. If the purpose is to establish typical laboratory performance then z Scores or Deviation from the Mean are appropriate. If data is analyzed by both method and laboratory, then method comparison data can be developed. However, inappropriate data analysis can easily lead to improper conclusions and misrepresentation of laboratory performance.

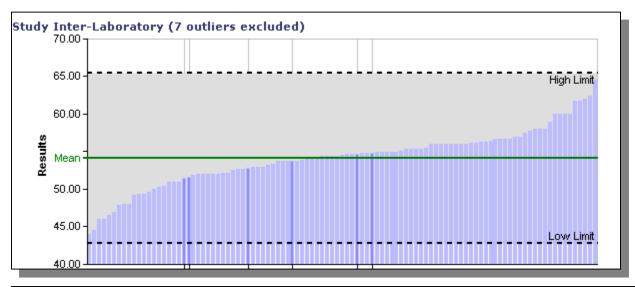
If we look again at the USEPA procedure for proficiency testing which evaluates laboratories based upon regression equations to develop an "expected" Mean and "expected" Standard Deviation, we can see that all of the actual data in the study is lost. Since 1999, when the USEPA privatized its PT programs, the limits have been calculated from data developed in EPA operated programs throughout the 1990s. During that period, the Agency used a complex and robust statistical procedure to estimate laboratory Means and Standard Deviations; however, the procedure tended to underestimate the Standard Deviation, and a significant number of laboratories failed even though the Agency was using limits set at Mean±3SD for WP and Mean±2SD for WS studies. This gave, and continues to give, the impression that general laboratory quality is poor. In fact, many of the regression equations used by EPA to set limits had correlation coefficients of less than 0.7 and were questionable at best.

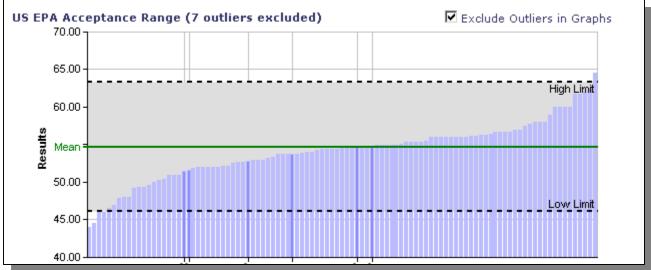
Comparison of Actual vs. EPA Estimated Standard Deviations from DMRQA Study 20 (Data set includes more than 2,000 laboratories)

	St	andard Deviatio	n	
Parameter	EPA Estimate	Actual Study	% Difference	Lab Pass Rate
Biochemical Oxygen Demand	17.6	28.4	61	91.99
Carbonaceous BOD	16.8	25.1	49	94.44
Chemical Oxygen Demand	10.5	38.9	270	87.63
Orthophosphate as P	0.17	0.37	118	85.32
Total Kjeldahl Nitrogen	1.37	3.88	183	86.09
Aluminum	40.2	58.8	46	90.73
Arsenic	6.17	10.6	72	89.08
Chromium	5.48	7.38	35	89.38
Lead	15.3	20.8	36	90.21
Mercury	1.12	2.29	104	87.16
Vanadium	39.4	52.1	32	92.05
Zinc	16.8	20.3	21	89.29
Total Cyanide	0.057	0.098	72	85.99
Total Residual Chlorine	0.14	0.29	107	84.04
Oil & Grease	2.27	4.02	77	83.45

Unfortunately, NELAP uses a similar regression-based evaluation process. The NELAP regression equations have recently been revised to be based upon data developed since the 1999 privatization and have more reasonable limits for correlation coefficients. These new limits take effect on June 1, 2005, and it is expected that they will improve the laboratory pass percentages for most WS and WP parameters. However, even with the new limits, the NELAP method of laboratory evaluation against estimated parameter statistics results in the loss of the real data that is available in the study.

Analytical Products Group, Inc. (APG) as a NIST accredited PT provider operates twelve EPA/NELAP compliant WP studies and six EPA/NELAP compliant WS PT studies a year. However, as a benefit to our participating laboratories, APG reports both EPA/NELAP required limits and the actual interlaboratory statistics based upon the methods of the Harmonized Protocol. This allows a laboratory to better understand of its relative performance compared to other participants in the program. It also allows a laboratory to evaluate the quality of the EPA or NELAP limits based upon actual study data. Interlaboratory z Scores show laboratories quantitatively how their performance compares to other laboratories running the same sample. Since method data is reported for all laboratories and results can be sorted by method they can better understand the limitations of the methods they are using. Similarly, by providing z Score plots of all data in the study for both the EPA/NELAP limits and the actual interlaboratory limits, laboratories can understand when they fail an EPA limit that is inappropriate and avoid unnecessary corrective actions.





WP Trace Metals Copper

Lot Number: 41592-41593 Authority: Regressions, NELAP Code 1055

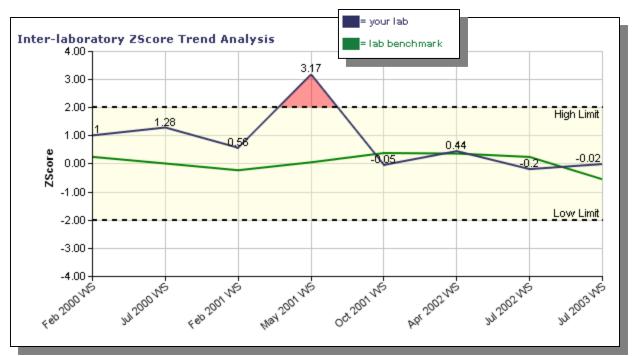
Method: EPA220.2 Technology:

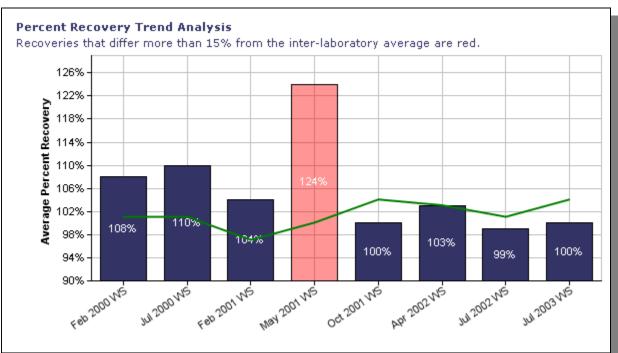
	Reported		Assigned	Percent	Certified
Evaluation	Value	Units	Value	Recovery	Value
Acceptable	51.5	ua/L	54.6	94.15%	52.3 +/- 0.29

	Study		Historic
	Inter-laboratory	Regressions	Performance
Your ZScore	-0.684	-1.12	
Your Rank		35 of 63	
Total Studies	1	1	23
Total Data Points	111	111	1227
Mean	54.1	54.7	100.37%
Standard Deviation	3.80	2.86	5.15
Acceptance Range (+/- 3 SD)	42.8 - 65.5	46.1 - 63.3	84.9 - 116%
Warning Range (+/- 2 SD)	46.5 - 61.7	49.0 - 60.4	90.1 - 111%
Average Percent Recovery	99.08%	100.18%	100.37%
Relative Standard Deviation	7.02%	5.23%	5.15%
Average Percent Acceptable	<u>Review</u>	<u>Review</u>	95.46%

In this case the EPA regressions under estimate the Standard Deviation by only 6% but it results in an additional 5% of participating laboratories failing the evaluation.

A fundamental failure of PT programs is that, much like a financial statement, they tell you a great deal about a laboratory at a single point in time but nothing about what happened before or after the study. However, by providing participating laboratories with plots of z Scores and percent recoveries over time against the average performance for the same measures, we have found that valuable information regarding trends in performance can be demonstrated. This is important if quality issues are to be found and corrected before they become accreditation failures. These same graphs can be used to demonstrate to an auditor that corrective actions on a particular parameter have been successful and that appropriate quality levels have been restored.





	Your Laboratory	Inter-laboratory Benchmark
Total Data Points	8	
Average Percent Acceptable	87.5%	90.39%
Average Percent Recovery	105.77%	101.3%
Absolute Median ZScore	0.5	0.1368

It is clear that the participating laboratories can gain a wealth of information by having the actual interlaboratory statistics from a PT study. It is also true that the regulatory agencies can also find this data valuable. The Agency has used interlaboratory data to demonstrate regulatory method performance for many years. EPA Method Study Number 1 was based on the classical methods of BOD and COD. However, many of these studies were based upon very limited data sets and were operated under tight controls that did not represent typical laboratory performance. For these reasons, the interlaboratory data quoted in many regulatory methods is inconsistent with performance in most environmental laboratories. Unfortunately, many of these limited data sets have been used to establish Quality Control Limits for the methods. The Office of Water recognized the value of the data available in the WS and WP studies, and within the past ten years, summarized the data as typical performance. Unfortunately, the Office used the results from the biased, robust statistical procedure used to set limits rather than re-analyze the original data sets which would have been more useful.

When the EPA privatized its PT program in 1999, it did not require the NIST accredited PT providers to collect method data in a useable format. However, NELAP, who accredits laboratories based upon matrix/method/analyte does collect this information. Since the focus of the NELAP PT programs has been laboratory control rather than environmental research, the data has never been analyzed by method, and to a large extent, the data has been ignored. Since NELAP data is within the public domain, it should be ready available. The NELAP PT Board currently has a project to establish a national database of NELAP PT data which could provide this information in the future. Proper analysis of this database could provide a wealth of information about the actual performance of the regulatory methods and shed new light on the actual Quality of the environmental data that is used to make critical decisions.

Building a Quality System In a FIFRA Lab

"Some people change their ways when they see the light; others when they feel the heat." This statement demonstrates that you can change first, or you can change last, but for progress to occur change is inevitable. As the use of pesticide residue analysis data becomes more widely used to make global, national, and state environmental policy decisions, laboratories are being driven to change how they operate by adopting or being accredited to a national or international standard on laboratory quality. Laboratories involved in Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) work, and the policy makers that use their data, need quality assurance that is both defensible and definable because this work often involves the protection of health and/or the environment. Due to these combined pressures, laboratories supporting the United States Environmental Protection Agency (US EPA) FIFRA compliance and enforcement work are looking at laboratory accreditation. FIFRA labs are unique because available methods rarely meet the complete needs of requests for analyses, the test requests are variable throughout the year and from year to year, and the client often needs the results as fast as possible. The unplanned nature of the work and the wide variety and variability of analyses performed to support FIFRA related activities has kept state labs from adopting a single model for laboratory accreditation. However, the Michigan Department of Agriculture (MDA) Laboratory Division, Pesticide and Environment Section (P&E) has begun the process of quality assurance through standardization by adopting the International Standard on laboratory competence (ISO 17025). ³ P&E chose the ISO 17025 standard in part because it is becoming widely accepted by many accrediting bodies such as the American Association of Laboratory Accreditation (A2LA) and the National Environmental Laboratory Accreditation Program (NELAP). ⁴ In addition compliance to this standard was preferred because incorporated in its design is the flexibility paramount for efficient, high quality results in a FIFRA lab environment. In the process of becoming compliant to this standard, P&E's experiences discussed in this paper create a model for building and implementing an ISO 17025 quality system in a FIFRA lab.

Building a quality system is a common thread that runs through a variety of accreditation programs and is the foundation of compliance to ISO 17025. A quality system is, in short, "saying what you do and doing what you say", and putting it in writing. One of the first hurdles to jump in creating P&E's Quality System was addressing the variety of documents that guide P&E's pesticide residue analyses. In addition to specific US EPA FIFRA work, P&E serves other clients for residue analysis, some of which are Michigan police agencies, the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), various

^{1.} Quote by Caroline Schoeder, Thinkexist.com

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and
 Cosmetic Act (FFDCA) As Amended by the Food Quality Protection Act (FQPA) of August 3, 1996,
 Unites States Environmental Protection Agency, Office of Pesticide Programs.

^{3. &}lt;u>Michigan Department of Agriculture Laboratory Division Strategic Plan</u>, January 2003

^{4. &}lt;u>NELAC Quality Systems: The Integration OF ISO/IEC 17025 and PBMS,</u> by Scott D. Siders, Division of Laboratories, Illinois Environmental Protection Agency; EPA 20th annual Conference on Managing Environmental Quality Systems.

university research departments, and Michigan governmental bodies responsible for urban and environmental initiatives. Several documents related to quality assurance (QA) direct P&E's activities for these projects such as Quality Management Plans (QMPs), Quality Assurance Project Plans (QAPPs), USDA Pesticide Data Program procedures, state civil service rules, state laws, and department and division policies. P&E began to define its quality system by bringing all of those documents together in a single P&E Section Quality Manual. The quality manual is the backbone of the quality system because it holds the basic policy statements and definitions related to all the laboratory practices that impact data quality. For P&E, the best way to bring the numerous client needs into a quality manual was to keep the quality manual general, listing broad policy statements, but using it to point to the specifics of laboratory operations by referencing standard operating procedures (SOPs). By keeping the specific instructions for tasks and analytical methods as separate documents from the quality manual, the quality system can be revised as needed in pieces, making the task of periodically updating the system easier.

While the general nature of the P&E Quality Manual will make the revision process easier, the original draft of the document was a daunting task because of its comprehensive nature. According to ISO 17025, all of the laboratory's quality system policies and objectives shall be defined in a quality manual which includes an overall quality policy statement and defines the roles and responsibilities of the quality manager and technical management.⁵ In order to ensure that our P&E Quality Manual met the fifteen management requirement sections and the ten technical requirement sections listed in the standard, we organized our document using the ISO 17025 outline. In addition to following the outline of the standard, we purchased software from SHOO Quality Assurance Manuals Incorporated ⁶ that was designed for building a quality manual according to ISO 17025. The software provided a template quality manual with topics separated according to the ISO 17025 model. The software also provided suggested text and example SOP references for each section. Use of this program provided the essential organization needed to design a quality manual consistent with ISO 17025 and allowed contributors to focus on content rather than design. In many cases the information in other P&E quality documents could be "cut and pasted" electronically into the document, which kept the quality manual consistent with current P&E policies and procedures. Because the software quality manual model was adopted Laboratory Division wide, each section quality manual remained consistent in design with the over-all Division Quality Manual. In addition, P&E was able to borrow example language and procedures from another laboratory section that was in the process of applying for ISO 17025 accreditation. Because ISO 17025 was designed for use by a variety of laboratory types, some of the specific policy-related SOPs referenced in the quality manual quality manual were easily adapted from other sources. However, P&E designed, from the ground up, procedures to handle unique FIFRA lab concerns for core elements of the standard, Training, Method Validation and Approval, Document Control, and Corrective and Preventive Action. 7

^{5.} International Standard ISO/IEC 17025, First Edition 1999-12-15, General Competence of Testing and Calibration Laboratories

^{6.} www.e-shoq.com, SHOQ Quality Assurance Manuals Incorporated

^{7.} International Standard ISO/IEC 17025, First Edition 1999-12-15, General Competence of Testing and Calibration Laboratories

The first core element discussed is the Training portion of the standard. ISO 17025 requires that the laboratory have a procedure for documenting employee qualifications, identifying training needs, and for authorizing staff for specific tasks. Employee qualifications are generally addressed by maintaining an updated credential file which includes the staff member's curriculum vitae, certificates from training, and civil service hiring records. However, identifying training needs to pre-qualify staff and pre-authorizing staff for a particular analysis can be difficult in an unpredictable environment. P&E has attempted to address this situation in two phases, in-house training grids, and combined competencies. The two phases of the training plan take advantage of the fact that even new analytical sample analyses often use steps that are the same or similar to steps in old methods. First P&E staff who are most experienced in performing a method are asked to define the most critical steps of that process and put them into a training grid (appendix 1). This grid is then used to document in-house training. The training documented on the grid provides competence records and approval to do work for a specific method. Once the trainee has successfully completed a training grid, Phase two of the plan takes the data from the grid and creates a combined competency spreadsheet. This spreadsheet shows the analyst as competent and approved to perform any of the critical steps related to the methods listed on the grid, even when these steps are part of another method. P&E's use of the grid and spreadsheet, added to the employees' general credentials allows P&E to demonstrate competence and approval to perform new methods as emergency situations occur. This flexible process for achieving demonstrated competence and pre-authorization to do work is a good fit for the FIFRA lab environment.

Similar to the training pre-approval and prequalification concerns, FIFRA labs have difficulty in meeting another core element of the standard, pre-approval and pre-validation of methods. P&E often faces the circumstance of having to develop or modify analytical methods in a relatively short time to solve questions of pesticide misuse that may have resulted in harm to health or to the environment. Although pesticide producers (Registrants) provide extraction methods to the US EPA, the methods provided do not usually work well for FIFRA compliance and enforcement projects. One of the major reasons registrant methods do not work in a real world setting is that the samples are usually submitted when the pesticide is not being applied as intended. For example, registrants do not submit a method for pesticide residue drift on tennis shoes, prize rose bushes or children's play toys. P&E answers the needs of FIFRA analysis requests by adapting currently available methods whenever possible at the time the concern presents itself. The need to adapt or develop methods for pesticide use investigations requires a process for method pre-approval and validation that is different from production oriented labs, whose protocols and methods are approved and defined by their client.

Pre-approval of methods required by the standard involves Section method approval and client approval. P&E approval to use a method occurs when an SOP for currently and commonly performed method is approved for use by the Section Supervisor. As much as practicable, P&E defines the known QA measurements of these methods from past uses. Often a method approved for use with a specific group of pesticides is modified for a new, similar pesticide residue. When these modifications are minor, they are defined on the extraction batch sheet. Once a minimum

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⁸ International Standard ISO/IEC 17025, First Edition 1999-12-15, General Competence of Testing and Calibration Laboratories

level of QA verification is achieved, the modification is then added to the method and the method is considered approved for the new residue. P&E addresses the issue of client preapproval for use of specific methods by creating Laboratory Project Profiles (LPPs) (see appendix 2). ⁹ These LPPs list what methods will be used for defined analyses and specify that new methods maybe developed for unforeseen analysis requests.

Much like the procedure for documenting method approval, P&E uses a flexible model for defining method validation. P&E achieves the flexibility needed for validating methods on a wide variety of analyses by creating a client-driven, tiered approach. The variety of levels of method validation are defined in relation to the client's use of the data. P&E defines and documents these levels of acceptable validation in each client's LPP. For FIFRA work, P&E has created a Use Investigation (UI) LPP. For large-scale UI projects where the client plans to monitor an area suspected of contamination, the level of method validation and quality assurance is well defined. These planned monitoring projects usually have the expectation of a large number of samples, and ample notice prior to sampling, and as a result P&E will agree to validate a method by performing a reasonable number of laboratory spikes to determine a calculated limit of detection (LOD) in the LPP. To cover other less-defined situations, P&E may build into its UI LPP language that requests the client specify the level of QA and related validation necessary to meet their needs. For example, when a suspected sample residue has a known tolerance in the sample type, P&E has met the client's QA needs and improved its efficiency by focusing its resources on demonstrating that it can, within a defined confidence, accurately detect that tolerance level rather than performing an LOD study. However, Use Investigation LPPs also attempt to take into account the large portion of emergency sample testing requests. P&E emergency samples are defined as samples that are due to arrive within hours to a few days often because intentional or accidental poisoning, using a pesticide, is suspected. For these cases the level of QA that P&E has defined in the UI LPP is the determination of an estimated rather than a calculated LOD. P&E determines the estimated LOD by running a few test spikes using the best available procedure. This process of estimating an LOD is P&E's process for answering ISO 17025's requirement for pre-validating in-house methods for the unique environment of emergency sample analyses. When these cases occur it is helpful to the lab to have a plan in place to easily access the most current versions of approved methods and to document method modifications and development.

P&E defined another core element of ISO 17025 by creating a procedure for Document Control that ensures that staff use the most appropriate and up-to-date information when performing assigned tasks. While document control is most relevant to data quality when analytical methods are updated to improve efficiency or to resolve data quality problems, this process is imperative for producing efficient, high quality data in a FIFRA lab environment. P&E's document control procedure centerpiece is the process of creating a master list of documents to keep track of the documents that define its quality system. While the main QA documents for P&E are its Section and Division Quality Manuals, the QMP, and the QAPP, the master list is most beneficial for tracking analysis method SOPs. The master list is a document that accurately identifies all of the documents that pertain to data quality, and it includes all the approved analysis methods. P&E's master list includes the documents' name, approved version, and storage location. By documenting the approved version of a method, P&E can track changes that occur when methods

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⁹ Section LB1-07 of Michigan Department of Agriculture Laboratory Division Geagley Quality Manual.

are modified for new compounds or matrices. Initially, minor method changes are documented on an extraction batch sheet; however, these changes are intended to be added to the appropriate SOP when practicable. Also, when method development for a new residue occurs, the initial method is documented on QA batch sheets. Once these methods are fleshed out and approved for the intended use, they are written up in the Section SOP format and placed on the Section master list. Also, whenever QA problems are apparent, whether they arise from attempting to lower a method LOD to fit client needs or adapting the method to a new technology, the modifications result in an updated version of the old SOP. These preventative actions and corrective action modifications are tracked through the use of the master list.

A final core element of ISO 17025 that has unique considerations for a FIFRA lab is Corrective and Preventative Action. As previously discussed, FIFRA lab work does not usually result in a large number of samples being analyzed, so normal or expected results are harder to define. For example, the creation of control charts with warning limits based on standard deviations is a common practice in production oriented environmental labs; however, the small group of samples common-place for FIFRA work prohibits useful statistics necessary for creating these charts. As a result true control charts are not the best tool for determining when a process is in control or requires corrective action. P&E attempts to answer the question of whether a process remains in control by using Spike Recovery Charts (see appendix 3) and instrument daily check solutions. Spike Recovery Charts are modified control charts because they still record various QA sample recoveries, but no statistical controls are applied. In addition, a single Spike Recovery chart may record data from spikes at various levels, with long time intervals between data points. However, a spike recovery chart is a useful tool in the FIFRA lab environment because it helps to define estimated LODs for a given procedure and raises a "corrective action" red flag if past performance cannot be met. To help judge whether instrument changes are the cause for variance in method performance, P&E, where possible, has incorporated instrument daily check solutions to help determine when maintenance or trouble-shooting is needed to obtain the best possible sensitivity for analysis. The daily check solution data is kept in binders so that information can be compared over time. In the P&E section specific staff members are charged with maintaining specific instrument systems; however, all staff are responsible for performing a variety of sample analyses. Because of this division of work, for preventitive and corrective actions to occur effectively, P&E must have an environment and plan that promotes good communication among staff.

Improving communication between P&E staff internally and with their clients externally was the final piece of the puzzle necessary for our FIFRA lab to develop and implement an ISO 17025 compliant quality system. Implementation of a quality system requires it to be a "living" system, rather than an unread book on a shelf. Creating a "living" quality system required that P&E put plans in place to keep staff apprised of the current policies and changes to the system, and provides a way for staff to have input into the system. P&E has improved its link between the quality system documents and its staff by appointing an internal deputy quality manager. This person's function has been to assist the Section Manager with updating quality documents and acting as a section resource for staff who are involved in creating or using quality system documents. Whenever policies are updated to comply with ISO 17025 or an internal audit demonstrates deficiencies with current policies, the P&E Deputy Quality Manager has updated staff thru meetings or staff training exercises. In addition, P&E held staff brainstorming sessions

to involve staff in crafting some of the new SOPs needed to comply with ISO 17025. These meetings allowed staff to become familiar with ISO 17025 terminology, client generated quality documents, and the section quality manual. Through P&E's efforts to get everyone on board in creating and adopting a ISO 17025 compliant system it is easier for staff to help with assessing methods and practices in relation to client needs; this staff input helps P&E meet the client awareness component of the standard.

Along with staff awareness of the quality system, built into the design of the ISO 17025 standard is the requirement to focus on client needs and education. This important principle has been beneficial to P&E because it saved the laboratory time and money by bringing the client into the planning process. It is still the nature of FIFRA laboratory analyses to have cases where the request for information changes. For example, the initial request may be, "Is the analyte in question present?", and then it becomes "What else did you find?" Moreover, once a compound is found, the client usually requests quantitation. At the end of the process FIFRA labs are often asked, "What does the number mean?" This question is important to state laboratories and their clients who are involved in FIFRA enforcement actions because the answer often determines what the client does next. As previously discussed, P&E has created a UI LPP that attempts to identify the quality plan for FIFRA work for the year. However, P&E attempts to have informal discussions with clients to help them understand the goals and limitations of the analytical methods chosen to do their work. These informal discussions that occur throughout the year often result in a new LPP for a new project or modifications to the existing LPP; however, the primary objective of these discussions is to help the lab efficiently meet the clients' intended use of the data.

In addition to the need to build client relationships, P&E has benefited from the informal partnerships that have developed between FIFRA labs. These informal relationships have helped P&E build its ISO 17025 compliant system by providing additional resources for method development, and training and expertise for new instrument techniques. The low but potent application rates of newer pesticides has required P&E and other FIFRA labs to purchase a variety of increasingly sensitive and complex analytical equipment. Because these labs share information on method development for these techniques with other labs that perform similar analyses, the training time to perform these new analytical techniques has been greatly reduced. In addition, where pesticide misuse events have occurred that cross state lines, P&E has been able to work with its other state lab partners to discuss data quality objectives and results. Because many of these state FIFRA labs are working towards ISO 17025 compliance, this information-sharing process will be enhanced in the future.

In conclusion, the flexibility inherent in the ISO 17025 model is the key to applying it to the FIFRA lab environment. The model described above attempts to answer many of the concerns a FIFRA lab environment creates when an ISO 17025 compliant quality system is built. As the national and global need and uses for pesticide data grows pressure for FIFRA labs to comply with a single quality assurance standard will increase. Moreover as the technical expertise demands increase and resources available to State FIFRA labs shrink, having a single quality system adopted by FIFRA labs will add the ability for these labs to easily provide their clients with quality assurance when they need to share methods and expertise. P&E's model helps to demonstrate how the ISO 17025 standard may be the best tool in place to answer this need.

FIFRA lab agreement to the ISO 17025 model for quality assurance inevitably leads to the process of accreditation. Accepting an outside accrediting body is another hurdle for state FIFRA labs to address. While ISO 17025 is increasingly the standard model chosen by accrediting bodies, the degree to which an accrediting body will chose to maintain ISO 17025 flexibility is not clear. However The ISO 17025 standard defines its goal by stating that, "The use of this International Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures". This is clearly the goal and need of FIFRA labs and it will be incumbent upon them to work with an accrediting body that understands this goal. Moreover, because imposition of a rigid quality structure would be a hindrance to FIFRA labs and their clients, P&E has begun the process of changing first to ISO 17025 rather than changing last to a standard that won't easily fit their work.

Appendix 1

	College Cton	Date	Timber	Date		How and When
4	Critical Step	Observed	Trainer	Performed	Trainer	Measured
1	Manifold Setup					
3	Use of Standards				-	
	Spiking Registering of Speedick					
4	Positioning of Speedisk			_		
6	Use of Speedisk waste removal	_			-	
7	Methanol activation of Speedisk	1				
8	Drying step					
9	Sodium Sulfate Set-up/Transfer					
10	N-evap Concentration\solvent exchange					
2	Sample hold times		5.2.			
	Important Concepts	Explained- (date)	Explained By	Explained To	Understood	
2	Sample Receiving process Sample hold times		5.0		7	
3	Sample Storage			5 (17		
4	DCM gas buildup and release					
5	vacuum damage to Speedisk			N.E.		
6	Extract Storage					
7	Speedisk Activation					
irrei	nt version of Method distributed to Trainee:		Traine	e initials		
	e keeping and Safety issues addressed			Initials		

Appendix 2

LAB PROJECT PROFILE <Project Name>

Project Descriptor: LPP..... Date Initiated: Project Goal: Briefly describe the testing project as initially understood. Identify the requesting client(s) name and project goals as understood. Preliminary Review Information (see LB1-07): Enter the date of review and list attendees. Are accepted methods available appropriate for the tests requested? No Are staff available having the education and skills adequate to perform the method? Yes No Are laboratory resources sufficient to perform the test requested? Yes No Project Information: Number of Samples expected: Estimate the number of samples to be submitted along with a time range. Tests Requested: Briefly describe the tests to be performed and matrices expected. Priority: High, Normal or Low Priority. Address unusual staffing issues (i.e. all routine work canceled, overtime not anticipated, etc). Turnaround time: Estimate the turnaround time for completing testing and reporting on individual, groups and/or all samples in the project. Describe sampling criteria that must be met (i.e. sample size, Field Sampling: containers, holding times, temperatures, labeling, handling precautions, etc.). Enter any "descriptive language" agreed upon between the Client test request: section and the client for identifying the testing. This language would be expected to appear on sample submission forms. Sample submission form: Identify the form that will be used to submit samples. Test Methods: Identify all testing methods that will be used for the project. Describe how test results will be reported. List acceptable Reports: reporting language for each analyte. Sample Retention: Describe how samples will be handled after analysis. Project Outcomes: Information in this field should be proceeded by the date of entry (i.e. as of Dec. 10, 2001). Briefly describe the project accomplishments including the number of samples analyzed and a statement on results. Client Contact: Identify the client contact person and phone number. Lab Contact: Identify the lab contact person and phone number.

Appendix 3

Com	ooun	d Al	pha B	HC			Percent Recovery "*" indicates minor modifications or comments listed below																																
ate r/Mo/D	Batch #	Sample ID	Known Amt	Obtained Amt	Percent recovered	Intials	30 2	46	880	24	П	62	П		246	882	II	П	802	466	8	246	8	624	68	770	T	7.	224	П	130	246	58	, ROS	46	8 3	2	46	8
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Workshop Proposal: Implementing and Assessing Quality Systems for State, Tribal & Local Agencies

Length: 90 minutes - three main presentations with break and questions & answer

Presenters: U.S. EPA Region 5, Region 6 and Great Lakes National Program Office

Overview: Development, implementation and maturation of quality systems is rarely a straight & narrow road for most organizations. Often times, progress is viewed as moving 2 steps forward and one step backward. This workshop will discuss implementation issues and means of assessing quality systems for state, tribal and local organizations. The presenters will address practical means to alleviate roadblocks for implementing systems. The workshop will present a model for stages of implementing quality systems applicable to most organizations as well as lessons-learned based upon assessments of quality systems at various stages of maturation. The attendees should come away with not only a better understanding of common implementation issues but ideas which they may be able to utilize in their own quality systems.

Intended Audience: Federal, state, tribal and local agencies developing & implementing quality systems as well those who have QA oversight responsibilities for such organizations.

Contacts: Kevin Bolger U.S. EPA Region 5 312-886-6762 bolger.kevin@epa.gov Don Johnson U.S. EPA Region 6 214-6658343 johnson.donald@epa.gov Louis Blume U.S. EPA Great Lakes National Program Office 312-353-2317 blume.louis@epa.gov

Request: Prefer morning session (2nd slot >10AM) early in the conference (i.e. Wednesday) if possible

Next Generation Data Quality Automation in EPA Data Marts

Phil Magrogan, Chief Technology Officer, ITS-ESE Program, Lockheed Engineering

Abstract:

The EPA has assembled a set of tools and techniques to automate the generation of high quality subject focused "Data Marts." The first Data Marts for Air Quality and Toxic Release Inventory will use these automated tools to Profile, Transform, Cleanse, Secure, and Audit incoming data. The subject specific target databases will then present this information in user-oriented, metadata driven, web-based Data Marts. This presentation will provide an overview of the tools and methods used to develop the next generation of EPA Data Marts. Attendees will learn how to leverage EPA's investment in high quality Data Mart generation and how to replicate these same strategies in their own database systems.

The Design and Implementation of a Quality System for IT Products and Services

John Scalera – Chemist and Special Assistant to the Director, Analytical Support Branch, Office of Analysis and Access, Office of Environmental Information, US Environmental Protection Agency

Abstract:

The OEI Office of Information Analysis and Access (OIAA) is in the process of implementing a quality management system referred to as QAMME. QAMME, which stands for Quality Assurance and Management Made Easier, is an expert system that guides users in the documentation of management and quality assurance information related to product and service development for OIAA customers. At the present time QAMME is in a MS Word forms-type format. It guides the users through a series of question and tables to be completed by the user that captures data/information requirements, data/information reduction and analysis processes, the objectives and features of the product or service being developed, how success will be measured and identifies the customers for the products and services. QAMME will also allow one to account for the total amount of resources (FTEs and contract dollars) expended to develop a product or service.

Data Quality is in the Eyes of the Users: EPA's Locational Data Improvement Efforts

Pat Garvey - Facility Registry System National Manager, and Co-Staff Director of the Exchange Network Steering Board, US EPA Office of Information Collection

Abstract:

OEI is aggressively making 2005 the Year of Data. With that emphasis, OEI is making a concerted effort to improve the locational data on the facilities regulated by statute and those that are of environmental interest. Currently, over half of EPA's known regulated facilities do NOT have documented locational values that can be used with confidence by the Agency for mission related work. The Approach and Plan will strongly engage Programs, Regions, States and Tribes to achieve the desired Agency results of documented accurate locational values for all facilities of interest. Policies, databases, exchange methods, geo-spatial tools, and quality measures will all be used to address this lingering Agency data quality concern. Participants will gain a greater understanding of the EPA efforts on locational improvement, and hear how they can be involved in the multifaceted approach and efforts.

An Analysis of Styrene Release Trends

Cathy Pitts, Ken Hayden and Paul Tillman
Department of Statistics
North Carolina State University
Raleigh, NC

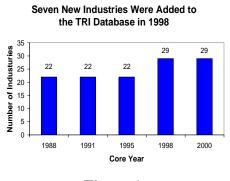
EPA created the Toxic Release Inventory (TRI) in response to the "Emergency Planning and Community Right-To-Know Act" of 1986. The public can access the TRI Explorer on EPA's website. The TRI Explore provides citizens with the means to identify industry routine reported releases of over 650 chemical materials. The database currently spans the years 1988 to 2002 and includes more than 20 industry categories. The intent of the TRI Explorer is to provide a tool to facilitate communication between the government, the public, and industry so that all parties can work together to identify potential problems, set realistic goals and evaluate progress. It is necessary to search groups of chemicals by "core year chemicals" when making year-to-year comparisons because EPA has made periodic changes to the TRI database. Styrene's release trend was the only one of the top ten 1988 core year chemicals in the year 2002 to increase from 1988 to 2002. Therefore, our objective is to use the TRI data to investigate trends in styrene releases into the atmosphere. We want to know how styrene release trends compare for the USA, North Carolina, and Wake County and what industries and facilities contribute to these trends. Many of TRI's industry categories reported styrene releases. Styrene releases by the plastic industry category increased from 1988 to 2002 and it was the highest category in 2002. In addition, we found that styrene release trends (in pounds per square mile) for the USA, North Carolina, and Wake County, NC increased from 1988 to 2002. North Carolina's trend remained consistently higher than that of the nation and it show a sharp increase between 1996 and 1998. Wake county's styrene releases were below that of the nation from 1988 to 1995 but increased sharply in 1996 to a value higher than the nation. Wake County's styrene releases were below from 1988 to 2002 except for the year 1996. We concluded that the 1996 increase in styrene releases was due to the start up of Majestic Marble and Glass Company. We recommend using the TRI Explorer to investigate which facilities may be responsible for the sharp increase that occurred from 1996 to 1998 in North Carolina styrene releases. It is important to remember that these results are based on only on estimates made by the facilities in 22 industry categories and that the results are not the actual exposure of citizens to styrene.

Introduction:

A Union Carbide facility located Bhopal, India accidentally released methyl isocyanate gas in 1984 and thousands of people. This tragic accident motivated congress to enact the "Emergency Planning and Community Right-To-Know Act" (EPCRA) in 1986. Section 313 of EPCRA authorizes the US Environmental Protection Agency (EPA) to create the Toxic Release Inventory (TRI).

The TRI database contains information on routine chemical releases of over 650 chemicals and chemical compounds by facilities in 29 industry categories. It spans the years from 1988 to 2002. The TRI Explorer allows the public to search this database and reports chemical releases in pounds. TRI Explorer is on EPA's website (http://www.epa.gov/triexplorer).

The TRI database can facilitate communication between the public, government and industry by providing the information necessary for identification of potential health concerns, setting realistic goals, and evaluating progress towards those goals. However, the TRI database has limitations: it does not include all industries or all toxic chemicals; facilities report calculated releases and not measured values; a reported chemical release by a facility does not equate to chemical exposure by the community.



Total Number of TRI Core Chemicals

800
600
600
299
316
1988
1991
1995
1998
2000
Core Year

Figure 1

Figure 2

EPA has periodically modified the TRI database since 1988. These periodic changes make year-to-year comparisons of releases difficult. The addition of new chemicals is one type of change, and this has occurred in 1991, 1995, and 2000 (Figure 1). The addition of new categories of industries is another type of change, and this occurred in the 1998 (Figure 2). (EPA has also made other types of modifications to the TRI database.) Therefore, EPA has grouped chemicals into 1988, 1991, 1995, 1995, and 1998 "core year chemicals.

We searched total air toxics release trends by the 1988 "core year chemicals" for the USA. We identified the ten chemicals that were responsible highest reported releases in the year 2002 (Figure 3). The top ten chemicals were methanol, toluene, styrene, xylene (mixed isomers), carbon disulfide, methyl ethyl ketone, certain glycol ethers, ethylene, carbonyl sulfide, and n-butyl alcohol, in that order. Styrene was the only one of these ten chemicals to increase.

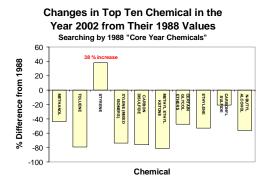


Figure 3

Styrene is released in the production of products such as fiberglass for boats, coating for sinks and bathtubs, and cultured marble for counter tops. Styrene releases are a health concern because it is a potential carcinogen.

Purpose

Our objective was to investigate the 1988 "core year chemicals" trends in styrene releases into the atmosphere for the USA, North Carolina, and Wake County, NC. We chose North Carolina and Wake County, NC because this is where North Carolina State University is located. We chose the 1988 "core year chemicals" because we wanted to compare across the years from 1988 to 2002.

The questions we wanted to answer were: What are the top industries categories that release styrene? How do USA, North Carolina, and Wake County styrene release trends compare? What are the styrene release trends of facilities in Wake County, NC?

Methods

In order to answer our first question, we made 14 searches by "industry". We limited our search to the 1988 "core year chemicals" and the USA for each for each search. However, we selected a different year for each search. We plotted the pounds released by the plastics industry for each year. We repeated this procedure for the transportation equipment then for the chemicals industry categories. All thee of these trends are in Figure 4.

Next, we used the TRI Explorer to search by "trends" for styrene release trends industry categories. We made one search for the USA report, a second search for the North Carolina report, then a third search for the Wake County, NC report. We limited our search to styrene and the 22 industry categories contained in the 1988 "core year chemicals". The reports contained pounds of styrene per year. We used Excel to convert pounds of styrene released to pounds of styrene released per square mile. Then we used Excel to plot pounds per square miles against each year from 1988 to 2002. We plotted the USA, North Carolina, and Wake County, NC on the same plot (Figure 5).

Finally, we used the TRI Explorer to make 14 searches by "facilities". We selected "Wake County" and "styrene" for each of our searches but varied the year. We plotted the pounds of each of the facilities in Wake County reporting styrene releases for each year (Figure 6). Note that some of the trend lines have gaps for a year. The TRI report entry was zero for these years. We interpreted a value of zero as a data entry error and, therefore did not use these entries into our plots.

Results

Figure 4 is a plot of the top three USA industry categories that release styrene into the atmosphere. The transportation equipment category reported the largest amount of styrene released into the atmosphere in 1988. This category's values remained close to 30% of all reported styrene releases into the air from 1988 to 2002. In contrast, reported styrene releases by the plastics industry category has increased from about 25% to over 50% during this time period, and the chemicals industry category has decreased from about 25% to less than 10%.

Figure 5 is Industry reported styrene releases have increased for the USA, NC, and Wake County from their 1988 values. The USA styrene release trend has risen from approximately 10 pounds per square mile to just under 15 pounds per square mile. Styrene releases in North Carolina have remained above that of the USA and there was a sharp increase in NC in 1998. Wake Co. was below the Nation from 1988 to 1996 and above the Nation from 1996 to 2002 and there was a sharp increase in Wake County in 1996.

Figure 6 is a plot of styrene releases by facilities located in Wake County, NC. Land-O-Sheen Inc. reported styrene releases from 1988 to 1990; Beautimar MFG reported styrene releases from 1988 to 1991 and from 1993 to 2002; Majestic Marble & Glass Co. reported styrene releases in 1994 and from 1997 to 2002.

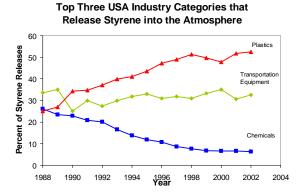


Figure 4

Styrene by Industries in 22 Categories: USA, North Carolina, and Wake County, NC

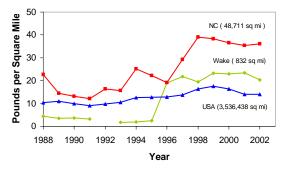


Figure 5

Styrene Releases by Facilities Located in Wake County, North Carolina

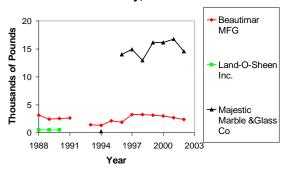


Figure 6

Conclusions

Our initial TRI Explorer report showed a 38% increase in USA styrene releases into the atmosphere reported by 22 industry categories from 1988 to 2002. This suggests that styrene releases into the USA are increasing. Therefore, we conducted our study under the assumption that USA styrene releases are increasing.

We used the TRI Explorer to investigate which industry categories might be responsible for this increase (Figure 4). Our results suggests that the facilities grouped into plastics industry category is may be primarily responsible for the USA increase in styrene, since the plastics industry increased from about 25% in 1988 to above 50% in 2002; and Plastics was the only one of the top three categories to show an increase.

We wanted to know if TRI Explorer would show a similar trend in styrene releases where we live (Wake County, NC) so we used the TRI Explorer to compare the North Carolina, and Wake County, NC with the USA (Figure 5). The reported styrene releases per square mile in the USA were similar to the trends in North Carolina and Wake County because they were higher in 2002 than in 1988. The reported styrene releases per square mile in North Carolina were higher that that of the USA from 1988 to 2002. In addition, North Carolina's trend increased sharply between the years 1996 and 1998. Wake County, NC, trend had a sharp in 2002 had increased from its initial 1988 values. Wake County's values were below the Nation from 1988 to 1996, then increased sharply to above that for the Nation from 1996 to 2002. Wake County's values were below that of North Carolina for all years except for the year 1996.

We used the TRI to investigate the facilities responsible for Wake County's 1995 to 1996 increase. We concluded that the startup of the Majestic Marble & Glass Co. from 1994 to 1996 was responsible for the increase. We recommend using the TRI Explorer to investigate what facilities and industry categories may be responsible for the sharp increase in North Carolina's styrene releases.

It is important to remember that these results are based on industry estimates of styrene releases and not measured values and that reported releases of styrene do not equate to actual exposure of citizens to styrene. These results suggest that styrene releases are increasing; therefore, EPA might consider investigating styrene releases.

Acknowledgements

We would to thank our North Carolina State University faculty mentor, William F. Hunt, Jr. and our EPA clients, Dr. Barry Nussbaum & Ms. Margaret Conomos.

Running Head: PROJECT KENTUCKY

Project Kentucky: A Look at Rubbertown and Its Air Toxins

Helen Ferguson

Spelman College

In conjunction with

Bianca McCollister Amanda Warner

Spelman College

Environmental Protection Agency, Region IV

July 8, 2004

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Abstract

Downtown Louisville, Kentucky is a hotspot for a vast amount of factories and industries. With just a two-mile radius, and a population that is mostly minority, 'Rubbertown' is a controversial area where concerns about pollutants have spawned the need for a study. This project is designed to investigate the air quality of Rubbertown and the surrounding areas. The data were analyzed to determine trends, patterns, and concentration levels of various chemical pollutants. This study investigates six chemical pollutants that pose health risks to the surrounding communities. Results indicate that the concentration levels for most of the chemicals are similar at sites spread all over the Louisville, Kentucky area and are therefore not just limited to the area within Rubbertown. Although Rubbertown has many factories and industries that produce chemical pollutants, it appears that there are other sources of pollution that pose problems for Rubbertown and its surrounding communities.

I. Introduction

Downtown Louisville, Kentucky, 'Rubbertown', is an area near the eastern coast of the Ohio River that encompasses a two-mile radius. Rubbertown contains a population of sixty-five percent minority and forty percent below the poverty line. Louisville was dubbed Rubbertown during World War II because it housed many rubber factories to quell the country's high demand for rubber (Environmental Protection Agency Region 4 [EPA 4], 2002).

For a city with such a relatively small geographical size, Rubbertown is currently heavily industrialized with such factories as Dupont Chemicals, Rohm & Haas, American Synthetic Rubber, Zeon Chemicals, Geon Chemicals, Ashland Chemicals, Marathon Ashland Petroleum, and many more contaminating facilities. The United States Environmental Protection Agency Region 4 (EPA) and the University of Louisville responded to the health concerns of the Rubbertown residents by conducting an air toxic monitoring program in and around the Rubbertown area.

The project was designed to compare the air quality of Rubbertown, the community nearest certain industrial areas, to communities farther away from industries. There was also intent to identify pollutants of interest and compare concentration levels in these communities. The initial hypothesis was that the concentration of air toxics will be worse in Rubbertown, the area of the most industry, than in the surrounding regions miles away from the industry. There were twelve original monitoring sites in and around Rubbertown. The three sites that are the focus of this study are two, six, and seven. These sites represent the areas of maximum exposure (site two), minimal exposure (site six), and a background site outside of speculated regions of risk (site seven) (Figure 1).

Site two measures the exposure of the Cane run neighborhood. This site measures the impact from the DuPont chemical company, Rohm & Haas, Elf Atochem, and American Synthetic Rubber. Site two is located right in the heart of the Rubbertown industries and is a duplicate site (site three) that was used for quality assurance purposes (EPA 4, 2002).

Site six measures the impact of human activities in the urban area on surrounding neighborhoods (EPA 4, 2002). The site is in the prevailing wind direction and receives the wind coming out of Rubbertown.

Site seven is the background site located twenty-five miles southwest of Rubbertown (EPA 4, 2002). Air passes through this region before it goes through Rubbertown. This site determines the quality of the air entering the Rubbertown district.

Six pollutants designated by the EPA as risk drivers, were chosen out of the 260 known pollutants of Rubbertown based on their means: arsenic, cadmium, Bromoform, 1, 4-dichlorobenzene, acrylonitrile, and chromium.

II. Methods

The Environmental Protection Agency, Region 4 and the University of Louisville collected the data that were used for analysis. Ambient air was collected in 15 canisters at 12 sites on every 12th day between April 2000 and April 2001 for evaluation. The collection period lasted 24 hours. This collection process was established to create a random sample of the ambient air. Science Ecosystem Support Division (SESD) analyzed the air samples for chemicals. Over 250 chemicals were tested and found in the ambient air (EPA 4, 2002). To reduce the amount of data, the data was sorted for the 16 risk drivers. Twelve of the risk drivers were found in the data. To further reduce the data set, descriptive statistics (i.e. means, standard deviations, maximums, and minimums) were taken for the chemicals at each

of the seven sites. This study investigates the chemicals with the highest means at site two (the maximum exposure site). Six chemicals were chosen for analysis: acrylonitrile, arsenic, bromoform, cadmium, chromium, and 1, 4 dichlorobenzene.

Before testing was conducted, outliers were removed from the data set. Outliers were determined by evaluating the readings for particular dates. The values for the dates were placed into a stem plot diagram. Values were dropped if they were 25% below the value that followed it. The same procedure was used for extreme high values. However, it was later shown that removal of the outliers had no significant impact on data analysis.

To evaluate the quality assurance sites, sites two and three, *t*-tests were conducted and the results were evaluated by the Bonforroni Correction was used. The correction value was determined to be 0.008.

After quality assurance testing, Pearson's correlations and correlation graphs were constructed between chemicals and sites, sites and seasons, and chemicals and seasons. These graphs were used to determine trends and likeness among sites, chemicals, and seasons. To calculate a value for seasons, the means for the season were taken. The seasons were defined in the following manner: spring (March, April, May), summer (June, July, August), fall (September, October, November), and winters (December, January, February). Graphs were done for the all the sites, but special attention was drawn to sites two, six, and seven.

III. Results

In accessing quality assurance, a series of t-test were conducted. A t-test for each chemical was conducted between sites two and three. The t-tests for each chemical between sites was found insignificant based on the Bonforroni correction of p = .008. Bromoform between

sites two and three, t(21) = 2.476 p = .02, is the closest to the correction value (Table 1). The t-tests' significance values suggest that the data from sites two and three differ significantly and imply that quality assurance is lacking.

Overall the data for all the chemicals shows that the pollution is a regional problem rather than a local concern. The graphs that compare the six chemical levels at the three sites had similar outputs. For example bromoform, at all three sites in the spring, has concentration levels between $7\mu g/m^3$ and $8\mu g/m^3$, and in the fall all sites peak between $9\mu g/m^3$ and $10\mu g/m^3$, and drop in the winter back down to $7\mu g/m^3$ (Figure 2). 1, 4 Dichlorobenzene has a similar trend. It also peaks with all three sites in the same season as well as drops at the same time (Figure 3). There are some instances when the sites further away have concentrations higher than site two, which is directly inside the industry. For example the concentration of cadmium, has a concentration at site six, east of Rubbertown, is between $0.001\mu g/m^3$ and $0.0012\mu g/m^3$, a much higher level in the fall than site two which is between $0.0002\mu g/m^3$ and $0.0004\mu g/m^3$. Note that the concentration of cadmium at site six had a magnitude greater than the levels at site two, within the industry, and site seven, south of the industry (Figure 4).

The seasonal graph of the concentrations of chemicals show a similar pattern to the graph of the chemical concentration throughout the duration of the monitoring, August 2001 to July 2001. Although bromoform may look like it has outliers in certain places, when shown on a graph with sites two, six and seven they match up almost identically (figure 5). This again shows that the concentration levels in all three areas were the same.

There was one chemical, arsenic, whose graph, which compares the sites, does not have an identical shape. Despite this fact it still confirms that the problem is regional. The graph for

arsenic by dates had places in the graph where site two was higher and then other places where site six is higher (Figure 6). This shows a fluctuation in the area where the concentration is the highest, and insinuates that the pollution is not solely due to the industries in Rubbertown, because there are chemical concentrations even higher outside the Rubbertown perimeter.

Correlations were done for each chemical among the three sites. For the correlations a correlation coefficient of r = 0.75 is considered very strong, r = 0.5 is strong, and less than that is weak. For most of the chemicals very strong correlations were found between sites two, six, and seven. The correlation coefficient between sites two and six for 1, 4 dichlorobenzene is r = 0.920 which is extremely high. Between sites two and seven the correlation coefficient is even higher, r = 0.976. For bromoform, the correlation coefficient between sites two and six is very strong, r = 0.825, and sites two and seven is higher, r = 0.977. Another chemical that shows a strong correlation is arsenic for sites two and seven, which is r = 0.579. Cadmium between sites two and seven has a correlation coefficient r = 0.747. The only negative correlation found is chromium, which has a negative correlation coefficient for sites two and seven of r = -0.001. Since this figure is so close to zero chromium, for sites two and seven, are not correlated at all (Table 2). High correlations between sites as well as the similarity in concentration between chemicals implies that the pollution is a regional versus local problem.

There are some exceptions to this conclusion, although few. For example, chromium, may be a local problem. Throughout the entire data, when chromium was run by seasons and by dates, site two directly inside Rubbertown is significantly higher than sites six and seven.

Although this contradicts the rest of the data, it is still very significant (Figure 7, 8).

IV. Conclusion and Future Works

All the data of this analysis seems to be pointing toward one resounding conclusion: if the residents of Rubbertown are at risk for adverse health effects from the industry in their area, then areas within at least a 25-mile radius are also at risk. The air quality problems of Rubbertown are not only a local problem that is strictly confined to Rubbertown's two-mile radius, but also a regional problem that affects many of the surrounding communities.

Each chemical has similar patterns at sites two, six, and seven. Since sites two, six, and seven have such similar patterns of chemical concentration, the wind going into Rubbertown is already contaminated before it blows through the industrialized area. It is possible that the contamination from the Rubbertown area may spread out for miles around, contaminating not only the air inside of Rubbertown, but also the outside area air.

The high correlations found between certain chemicals at two different sites go on to even further prove that Rubbertown's air quality is a regional problem. There are too many high correlations between the three selected sites for any assumptions of coincidence.

Chromium is the only chemical that seems to be a local problem. This is to be expected since chromium is important in chemical manufacturing, and Rubbertown houses a wide number of chemical manufacturers. This does, however, raise the question: if other chemicals are being dispersed away from Rubbertown, then why not chromium? The location of West Louisville next to the Ohio River, and the composition of the various chemicals may have a lot to do with the air quality of this area and the concentration of the chemicals at different sites.

The results of this project suggest a lack of quality within the data. The differences in the data between sites two and three, the quality assurance sites, are too great to be ignored. This

raises questions about the quality of the data as a whole if the data of the side-by-side quality assurance sites show so much diversity for the same readings. Future plans for this study, would be to further investigate the discrepancies between sites two and three. Since the sites of focus, sites two, six, and seven, seem to have the same air quality; a risk assessment for these areas would have to be done. Also, other chemicals, possibly from the list of risk drivers, would have to be examined to see if the trends are the same. The issues of Rubbertown are not just local but regional. More investigation is needed to determine the causes and possible solutions.

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 ezfacts/ezf232.htm.

Appendix

Figure 1.

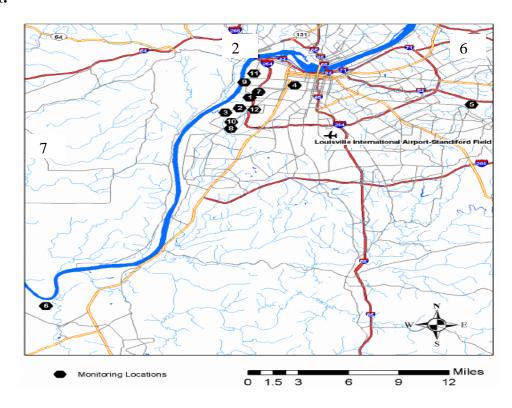


Figure 1. This map represents Rubbertown and the surrounding area. A number marks the sites of interest. Site 2 is in the center of Rubbertown. Sites 6 and 7 are located further away from Rubbertown.

Table 1.

N	t	Significance
18	535	.599
14	.671	.242
21	2.476	.022
12	-1.413	.185
14	659	.521
20	1.690	.107
	18 14 21 12 14	18535 14 .671 21 2.476 12 -1.413 14659

Table 1. A table of t-tests results. N is equal to the number of observations. P = .008.

Figure 2. Seasonal Trends of Bromoform for Sites 2, 6, 7.

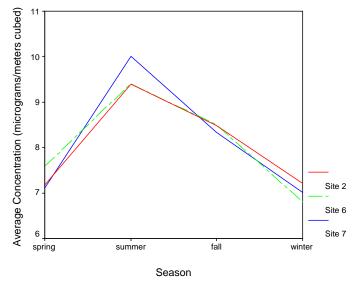


Figure 2. The seasonal trend of bromoform is seen across all three sites. Bromoform shows a strong peak in the summer months and shows a decrease in the fall, winter, and spring months.

Figure 3. Seasonal Trends for 1,4 Dichlorobenzene for Sites 2, 6, and 7.

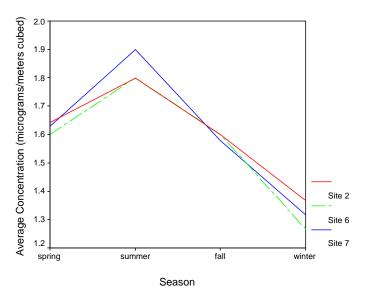


Figure 3. The seasonal trends for 1,4 Dichlorobenzene is seen for all three sites. 1,4 Dichlorobenzene forms a peak during the summer months and decreases during the fall, winter, and spring months.

Figure 4. Seasonal Trends for Cadmium for Sites 2, 6, and 7.

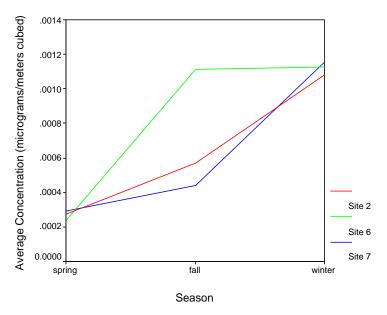


Figure 4. Sites 2 and 7 have the same seasonal trends. However, site 6 has a reverse trend than the other two sites. While sites 2 and 7 are down in the fall, site 6 is elevated.

Figure 5. Daily Trends of Bromoform by Site

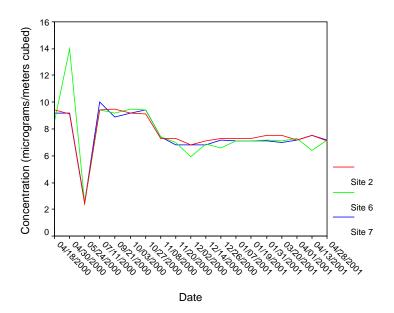


Figure 5. The daily trend for bromoform is seen across all three sites. The concentration levels are very similar on several dates.

Figure 6. Daily Trends of Arsenic by Site

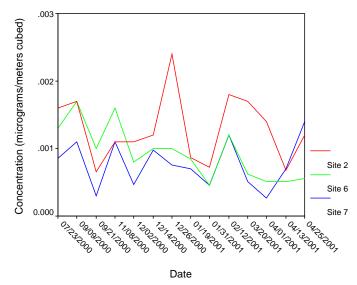


Figure 6. Site 2 is higher in concentration than sites 6 and 7 on some dates. Site 6 is also higher than site two and 7 on other dates.

Table 2.

Arsenic	Site 2	Site 6	Site 7	
Site 2	1.0	0.400	0.579	
Site 6	0.400	1.0	0.490	
Site 7	0.579	0.490	1.0	
Chromium	Site 2	Site 6	Site7	
Site 2	1.0	0.071	-0.001	
Site 6	0.071	1.0	0.489	
Site 7	-0.001	0.489	1.0	
Bromoform	Site 2	Site 6	Site 7	
Site 2	1.0	0.825	0.977	
Site 6	0.825	1.0	0.822	
Site 7	0.977	0.822	1.0	
1,4 Dichlorobenzene	Site 2	Site 6	Site 7	
Site 2	1.0	0.920	0.976	
Site 6	0.920	1.0	0.964	
Site 7	0.976	0.964	1.0	
Acrylonitrile	Site 2	Site 6	Site 7	
Site 2	1.0	0.077	0.049	
Site 6	0.077	1.0	0.682	
Site 7	0.049	0.682	1.0	
Cadmium	Site 2	Site 6	Site 7	•
Site 2	1.0	0.395	0.747	
Site 6	0.395	1.0	0.083	
Site 7	0.747	0.083	1.0	
· ·				

Table 2. A correlations table by site of each of the six compounds.

Figure 7. Seasonal Trends of Chromium for Sites 2, 6 and 7.

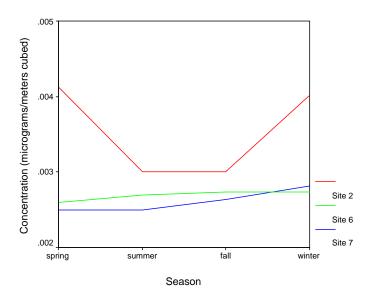


Figure 7. Chromium is higher in concentration at site 2 than the other two sites. The other two sites, site 6 and 7, are mirror images of each other.

Figure 8. Daily Patterns of Chromium for Sites 2, 6, and 7.

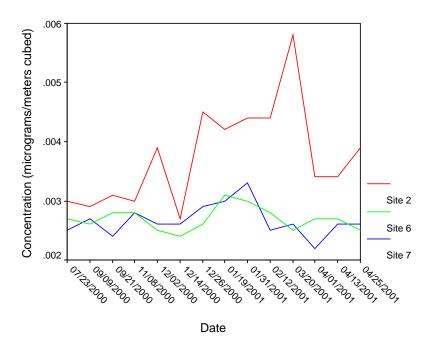


Figure 8. Site 2 is higher in concentration than sites 6 and 7. Sites 6 and 7 intersect on certain dates.

Alternative Methods of Graphically Representing Ambient Air Quality Data, Wind Speed and Wind Direction to Identify the Locations of Point Sources of Emissions

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Abstract:

When was the last time you stopped to think about the air that you are breathing? The EPA along with many other local agencies have spent millions of dollars in attempt to gain a better understanding of the pollution that is in the air, how it affects the population and where is the pollution coming from. My colleagues and myself and done extensive research in order to gain a better understanding of what is in the air. As in all research being able to explain your results in a way that people can understand is important. This paper will explain how you can take previously recorded data and graphical represent it in such a way that you can better understand it, and see where the pollution is coming from.

Objectives:

The objective of this study was to develop alternative ways to represent Ambient Air Quality Data, Wind Speed, and Wind Direction to identify the location of point sources of emissions over time.

Background:

The United States Environmental Protection Agency has developed a network of Photochemical Assessment Monitoring Station (PAMS) in 22 metropolitan areas across the United States. To record and measure the concentration levels of over 50 Volatile Organic Compounds (VOC), nitrogen oxides, and ozone, along with meteorological data. In addition to the PAMS network there are many local agencies that have their own network of Air Monitoring Sites that take hourly measurements of specific VOC, PM2.5, and other local pollutants that are of concern.

Normalization of Air Quality Data:

A known aspect of the Ambient Air Quality data is that greater wind speeds reduce concentration levels, because the wind flows across the site faster. Conversely, slow wind speeds allow the concentrations to build up. In order to remove the effect of wind speed we multiplied the concentration levels by the wind speed.

Abnormal Data:

Through previous research in Houston, it was determined that the top 2 percent of data could be classified as abnormal. This process used the Emission Inventory from Houston and tried to corroborate the emission inventory at two sites: Deer Park and Clinton by comparing the ratio of VOC to NOx from the inventory with the air monitoring data. The Emissions Inventory is based upon engineering estimates of the industrial processes and mobile sources on a typical day and it assumes that emissions are released at a continuous rate from the industrial sources. This assumption made it impossible to account for manufacturing mistakes, machine malfunctions, oil spills, and other malfunctions at industrial sites. Malfunctions will not allow emissions to be released at a continuous rate. By removing this abnormal data or the top 2% of the ambient air quality data it was found that the Emissions Inventory and the Ambient Air Quality Data matched almost perfectly. This was a tremendous improvement from the previous estimation that was off by a factor of 6.

Graphical Approaches:

Two different graphical approaches have been developed in an attempt to better understand the ambient air quality data recorded at these PAMS sites. Both of these techniques have advantages and disadvantages when compared to the other, but one can use both in conjunction with each other there is an enormous amount of information that can be seen. The first is a two dimensional graphic that has the normalized concentration levels (ambient air quality x wind speed) on the vertical axis, and the wind direction on the horizontal axis. The second approach is a three dimensional graphic with the normalized concentration levels on the vertical axis, the wind direction is on a circle in the x-y plane, and like the ripples in a pond the years are on different circles.

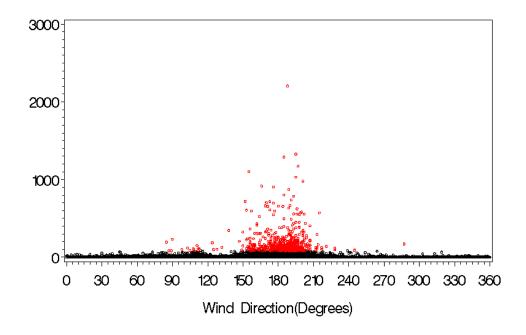
Two Dimensional:

The two dimensional approach was the first to be developed; it is in a standard graphical plot with the vertical axis being the concentration level of the VOC times speed, these values are normalized to take into account the effect that wind speed has on the concentration levels. The horizontal axis is wind degrees, going from 0 to 360. North is 0 and 360 on the graph which is on each end of the

plotting surface, 90 is east, 180 is south and 270 is west. These degrees correspond directly back to a standard compass. This graph accurately shows the concentration levels by corresponding points to the vertical axis, and the direction from which it is coming corresponds back to the point on the horizontal axis. With the previous research that my colleagues and I have done on distinguishing between normal and abnormal data (top 2%), the graphic is color coded to shows the separation. The top 2% are colored in red, and if you look at the graphics the red dots are generally plotted in clusters or spikes. The spikes of the red dots point directly at point sources of emissions that are emitting an excessive amount of pollution into the air.

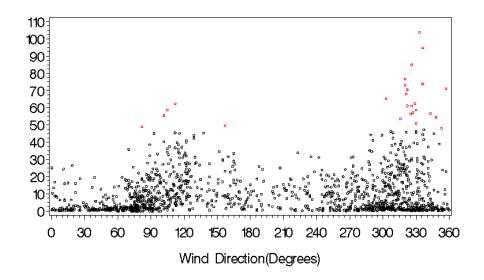
The following graphic is an example of the two dimensional plot. This graphic is for the Clinton PAMS site in Houston, Texas, for the VOC 1, 3 Butadiene. As you can see there is a well defined spike between the wind degrees of 150 and 210, south = 180. After showing this graphical presentation to our clients at the Texas Commission on Environmental Quality and the University of Texas, they responded by identifying the facility that was causing the problem. 1,3 Butadiene is used in the production on synthetic rubber for car and truck tires.

1,3 Butadiene plotted by Wind Direction for Clinton



The next graphic is another example of the two dimensional plot, it is for the Conyers site in Atlanta, GA. This site is located at a catholic monastery that is approximately 300 yards from a large grouping of trees. Isoprene is released from vegetation and is affected by temperature. Generally, higher temperatures relate to higher isoprene concentration. This graphic is pointing toward this cluster of trees.

Isoprene plotted by Wind Direction for Conyers



Three Dimensional:

This three dimensional approach is a highly complex approach that allows the representation of wind degrees in a compass like circle. Like the two dimensional approach the VOC concentration levels are plotted vertically, these values are normalized to take into account the effect that wind speed has on the concentration levels. This graphic also has been color coded to represent the abnormal data with red pillars and the normal data being blue pillars.

In an attempt to make the wind direction variable easier to read, wind degree were converted into functions of sin and cos.

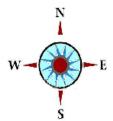
```
x = -1 *(sin * (2*pie*Wind Degree/360))

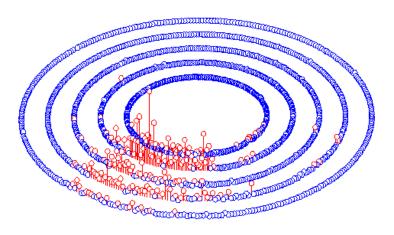
y = cos * (2*pie*Wind Degree/360)
```

These two functions convert the wind degree's into two variables x, and y. These two variables are points that correspond back to the unit circle. Because the unit circle counts around the circle counter clockwise, I had to multiply x by a -1 so that it counts around clockwise, just as the wind degree days do. Dr. David Dickey a professor at N.C. State University showed me how to do this.

After the conversion of wind degrees, the next step was to show how the normalized values (concentration level times wind speed) change over time. By adding a radius variable, into the equation the graphic now has concentric circles that compare years. This has great advantages over the two dimensional graph because you the trend in malfunctions. Are they being reduced and is air pollution changing over time? Every circle represents a different year, this graph represents data from 1997 through 2001 with the inside circle being 1997 and the outside circle being 2001. The following graph represents the Clinton site for 1, 3 butadiene (the same as the first two dimensional graph).

1,3 Butadiene for Clinton





Other Applications:

These two graphical approaches can be applied to other air pollution data. EPA has placed regulations on many pollutants that have been found to be harmful, including most notably fine particulate matter (PM2.5). The same type of graphics can be used to identify sources of PM2.5 emitters, and can be used to help regulate these sources and their emissions.

I have developed my SAS code in such a way so that it can be adapted to any data set with any pollutant. By changing the name to any of the 50 Volatile Organic Compounds, or any other pollutant recorded within a data set you can produce a different graphic.

Conclusions:

These two different graphical representations can be used together to allow an in-depth analyzes of ambient air quality data. These two graphical designs demonstrate the ability to locate point sources of emissions of individual VOC species and identify sources responsible for spills, upsets, malfunctions, and other uncontrollable events. This can help in enforcement of environmental

regulations and encourage the source to employ better environmental management practices. The source benefits by minimizing the loss of product caused by malfunctions, which is inadvertently released into the air. These graphical approaches have been developed in a manner that allows them to be applied to all types of air quality and meteorological data, and they can be used all over the world to enforce emission control regulations and help sources better manage their facilities by locating point sources of emissions.

Acknowledgements:

Dr. David Dickey, for taking the time to teach me the finer aspects of SAS and how to apply that knowledge.

Professor William F. Hunt, I have learned so much while working with you for the past two years, Thank you for all of your advise and guidance and making my experience working with you truly unforgettable.

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¹ Louise Camalier, Brendan Yoshimoto and Brian Stines, "A Statistical Method to Corroborate VOC Emission Inventories Using Air Quality Data – Applied to Houston and Atlanta.," Undergraduate Research Journal of North Carolina State University, First Edition http://www.ncsu.edu/undergrad-research/urj/. 2004.

Investigating the Effects of Airplane Emissions on Ambient Air Quality in Metropolitan Atlanta: The Impact of September 11, 2001 and the 1996 Olympic Games

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In cities with heavy air travel, airplane fuel emission is a significant contributor to air pollution and a potential threat to public health. During a temporary delay of air traffic after the events of September 11, 2001, Atlanta was one of few cities that kept air monitors on to measure air quality; this three-day absence of flights provided a basis for measuring the impact of airplane fuel emission on air quality. This exploratory analysis of emissions inventory in metro Atlanta before and after 9/11/01 reveals significant decreases in the emission of two compounds commonly found in airplane fuels in the three days following 9/11. In addition, emissions data from the summer of 1996 are explored. Analyses of wind direction identify sources of emission, and other hazardous compounds are examined for both time periods. Comparing these emissions data with local asthma statistics reveal important public health implications.

Is the Fine Particulate Matter Air Pollution "Non-Attainment" Problem in Hickory and Lexington, NC Regional or Local?

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Abstract

Particulate matter is one the United State's six criteria pollutants monitored by the Environmental Protection Agency. Specifically fine particulate matter measures 2.5 micrometers in aerodynamic diameter or less. This type of air pollution has been shown to cause increases in premature mortality as well as cardio-pulmonary disease. There are strict standards that each state must satisfy to be classified as an attainment area. These states are further broken into counties or slightly larger groups of counties that must meet these pollution concentration requirements. For an annual mean, the concentration must not exceed 15 micrograms per cubic meter. There is a daily max limit set at 65 micrograms per cubic meter. Two counties in North Carolina have been deemed non-attainment areas by the EPA. Both counties' three-year average concentrations of particulate matter have exceeded the annual average standard set by the EPA.

The North Carolina Department of Environment and Natural Resources needed to analyze concentration level data to determine if the non-attainment problems were regional or local. Three sets of data including continuous, federal reference method and meteorological data were examined.

Data management was the first step in combining all of these different forms of useful data together. Multiple statistical and graphical analyses examine whether a regional or local problem could be the cause of non-attainment.

Most of the statistical analyses show a regional and local component attributing to the concentrations in the non-attainment areas. However, there also seems to be differences inside the town of Lexington. This suggests a local component that could be pushing Davidson county or more specifically Lexington, NC into non-attainment. The possibility of only using co-located meteorological data with the particulate matter data is also addressed. Although a definite conclusion on the origin of influence for these monitors to be in non-attainment was not reached, several methods of examining the data show useful relationships and possible directional source locating techniques. These methods also utilize the half hour continuous concentration data for analytical purposes.

Background

Particulate matter air pollution is one of the six criteria pollutants of the United States. It is monitored all over the United States and in North Carolina on a county wide level. Fine particulate matter is defined as being particulate matter with 2.5 micrometers or less in aerodynamic diameter. These particles are small enough to enter a person's lungs when inhaled. Many studies have shown that an increase in particulate matter increases the premature death rate over a whole city. Particulate matter has been shown to cause heart and lung disease when exposed over a period of time. It is especially dangerous to people with existing heart and lung health conditions. Particulate matter also impairs visibility. These reasons cause particulate matter to be monitored very closely by the United States of America.

This type of air pollution is monitored using two different types of station monitors. One of them is sanctioned by the EPA and decides whether the area is below or above standard. These 24-hour average monitors are called Federal Reference Method monitors. These FRM monitors collect data every three or four days. They have a filter that is collected from the monitoring site and then shipped back to a lab to be weighed for the concentration level. Another useful monitor is the TEOM machine, or the tapered element oscillating microbalance. This monitor allows us to have continuous measurements. It records observations every thirty minutes, but remains on all of the time. The TEOM monitor provides an excess of data to analyze.

In North Carolina, there are more FRM monitors than TEOM monitors. The FRM monitors are located in most of our counties. TEOM monitors are located in more heavily populated areas. Standards have been set by the Environmental Protection Agency to protect the people from being exposed to high concentration of particulate matter for an extended time. There is an annual average standard of 15 micrograms per cubic meter and a daily max standard of 65 micrograms per cubic meter that must not be exceeded. The State department that watches over these numbers is the Department of Environment and Natural Resources. The Division of Air Quality is in charge of monitoring all of the counties inside North Carolina with the exception of Mecklenburg County. A local team monitors them.

In February 2004, all of the states had to submit the non-attainment areas to the Environmental Protection Agency. Later that year the EPA responded with a list of counties that were to be added to non-attainment areas. NCDENR designated that Davidson and Catawba County were to be non-attainment areas in North Carolina. Their three-year annual average had violated the 15 microgram per cubic meter standard. Later that year, the EPA grouped more counties into these designated counties based on the metropolitan statistical areas devised the Census Bureau. NCDENR has added more sites to these two counties to further analyze the problem causing non-attainment. Two sites in Hickory, one at the water tower and the other at a fire station include two FRM monitors and one TEOM monitor. Davidson County consists of three locations, the oldest FRM at the water tower that also has a TEOM monitor now, the oldest TEOM monitor at the Airport that also includes an FRM monitor, and a FRM monitor at the Fairgrounds in Lexington.

Objectives

The main objective was to determine whether the non-attainment problem was regional or local for these two locations. Four different types of data sets were given by NCDENR. They are the FRM concentrations for the past 3 years, TEOM concentrations in thirty-minute intervals for the past 8 months, meteorological data to accompany the TEOM data, and a speciated data set. The speciated data shows the composition of the particulate matter. These data sets have been manipulated and combined in some ways to help in examining this problem.

Using these four data sets we will attempt to show if these concentrations are occurring on a regional or local level for North Carolina. Since the two counties have been over standard for some time now, there are multiple monitors inside each of the non-attainment areas. The differences within the areas will be examined to show a local difference that may be present.

Our main purpose is to analyze the data to provide clues to NCDENR. This research is only for analytical purposes. There will be no decision that is based on this research. The Department of Environment and Natural Resources does not sanction it in any way. They have provided the data and have allowed us to present our findings to them in meetings at their headquarters. We hope to have provided some insight and ideas on why these counties are non-attainment areas.

Methods

The first goal was to get all of the data into a form that could be used for analyzing and comparing the concentrations. Two main data sets were created. The first was all of the data from the FRM monitors across the state, including multiple monitors in Catawba and Davidson counties. With this data set, a map of correlations was made from the perspective of both of the non-attainment counties. The older monitors were used to see if there was a spatial relationship between all of the FRM monitors in North Carolina. The Correlation between the counties is stronger when the color is darker on the map.



Figure A.1 FRM Monitor Correlation Map from Davidson County's Perspective



Figure A.2 FRM Monitor Correlations Map from Catawba County's Perspective

Days of the week were analyzed to show differences between the days in both non-attainment areas with the FRM concentrations. This difference was tested for statistical significance. Finally, the three new FRM monitors in Davidson County and two monitors in Catawba County were compared with one another to show correlations between the different sites inside each city. This could be used to show a local effects inside each county since the monitors were less than 10 miles from one another.

R-value	Lexington	Lexington	Lexington	Hickory	Hickory
P-value	Airport	Water	Fairgrounds	Water	Fire station
Observations.		Tower		Tower	
Lexington	1.0000	0.7246	0.9715	0.7813	0.9187
Airport		<.0001	<.0001	<.0001	<.0001
	45	45	43	40	45
Lexington	0.7246	1.0000	0.7138	0.6392	0.7410
Water	<.0001		<.0001	<.0001	<.0001
Tower	45	48	46	42	48
Lexington	0.9715	0.7138	1.0000	0.7658	0.8891
Fairgrounds	<.0001	<.0001		<.0001	<.0001
	43	46	46	40	46
Hickory	0.7813	0.6392	0.7658	1.0000	0.8139
Water	<.0001	<.0001	<.0001		<.0001
Tower	40	42	40	42	42
Hickory Fire	0.9187	0.7410	0.8891	0.8139	1.0000
station	<.0001	<.0001	<.0001	<.0001	
	45	48	46	42	48

Table B.1 FRM Concentrations Correlations between FRM Monitors

The other main data set that was created had the TEOM half hour concentrations and the meteorological data that was provided by NCDENR. Since the meteorological data was collected on an hourly basis, the observations were doubled to merge with the TEOM concentrations. This data set provided many observations to run statistical tests upon.

First, diurnal patterns were examined and plotted for all of the TEOM sites in North Carolina. This was done to show differences in the diurnal pattern of daily averages across the State of North Carolina. The orange line represents Davidson County and the green line represents Catawba County.

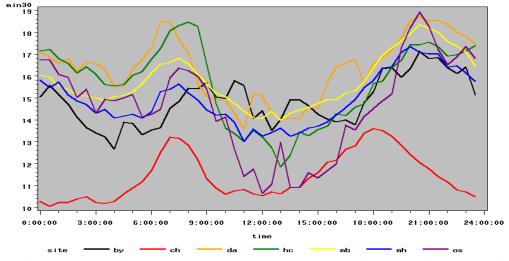


Figure B.2 TEOM Diurnal Patterns (Davidson = Orange, Catawba = Green)

After this, a technique was used to point to possible source locations using the meteorological data. This was done with the help of Bryan Stines. It can be shown that when wind speed is higher, concentration of PM fine is diluted into the air so it becomes smaller. Since there is an inverse relationship between the wind speed and the concentration of airborne particles, multiplying them together should smooth out the data. High particular concentrations when the wind speed is high are stronger than a high concentration in low wind speeds. This new variable was plotted against the wind direction amplifying the direction of heavy concentrations. This was done for both Counties, and more specifically the Airport site in Davidson County and the Water Tower site in Catawba County. Different colors were used for the initial concentrations to show their magnitude. These colors follow the AQI color code. Wind directions of 400 and 0 correspond to a measurement of calm or variable wind speed.

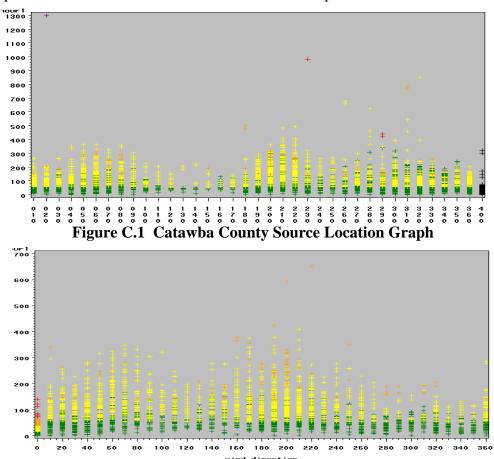


Figure C.2 Davidson County Source Location Graph

AQI Index Values	AQI Descriptor	Concentration range (24-hour ave.)	Color
0 to 50	Good	0 μg/m³ to 15.4 μg/m³	Green
51 to 100	Moderate	15.5 μg/m ³ to 40.4 μg/m ³	Yellow
101 to 150	Unhealthy for Sensitive Groups	40.5 μg/m³ to 65.4 μg/m³	Orange
151 to 200	Unhealthy	65.5 μg/m³ to 150.4 μg/m³	Red
201 to 300	Very Unhealthy	150.5 μg/m ³ to 250.4 μg/m ³	Purple

Meteorological data was sometimes co-located and other times it might have been from an airport site that was a few miles away, such as in Catawba county. Correlations between the meteorological variables were also examined to show if the meteorological data would be applicable from a different site. This was done in Charlotte and Raleigh, NC.

<u>Parameters</u>	Correlation Coefficients	
Wind Speed	0.69323	
Wind Direction	0.36299	

Table D.1 Raleigh Airport vs. Alternate Site Meteorological Correlations

<u>Parameters</u>	Correlation Coefficients	
Wind Speed	0.68070	
Wind Direction	0.48721	

Table D.2 Charlotte Airport vs. Alternate Site Meteorological Correlations

Using the TEOM data, diurnal patterns were plotted for each of the different days of the week. This was one of the most helpful analytical techniques used. These plots were made for two sites inside Davidson County, one site in Catawba. On these plots a 95th and 5th percentile were added to the average concentration value. This showed how the variation changed over the week. There were also color-coded averages to see if they were above or below the standard of 15 micrograms per cubic meter. If the average is red then it was over 15 and if it was black then it was below 15. They start with Sunday on the top left then move to Monday on the top right and follow to Saturday on the bottom left.

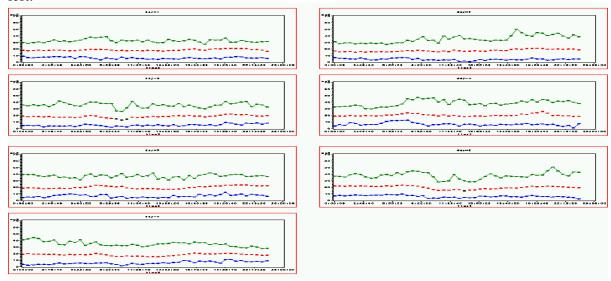


Figure E.1 Davidson Airport Diurnal Patterns by Day of the Week Figure D.1 Davidson Airport Diurnal Patterns by Day of the Week

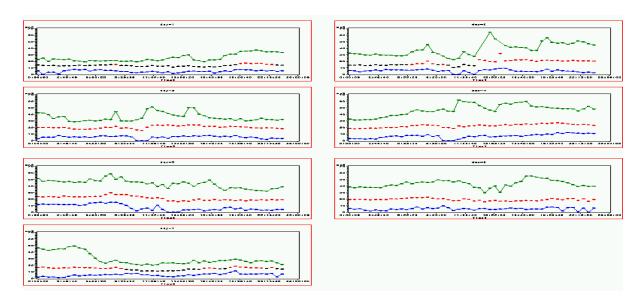


Figure E.2 Davidson Water Tower Diurnal Patterns by Day of the Week

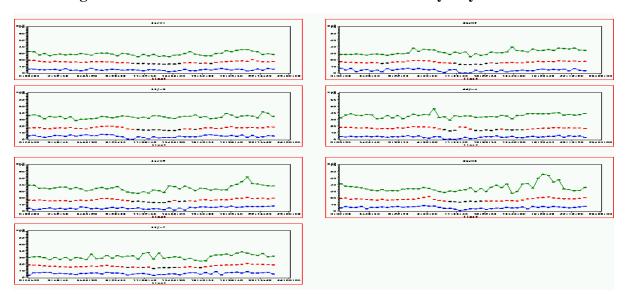


Figure E.3 Catawba County Diurnal Patterns by Day of the Week

Using this same idea, the new variable of wind speed multiplied by the concentration was plotted by wind direction for every different day of the week. This allowed us to see if the sources could be changing over the days of the week.

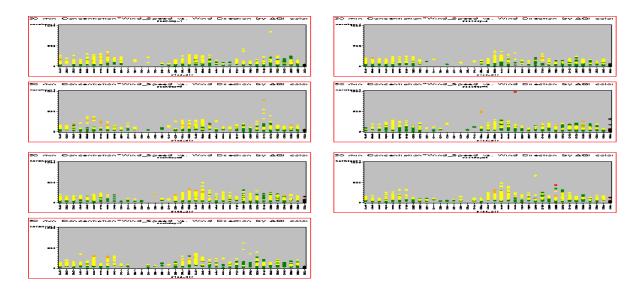


Figure F.1 Catawba County Source Location Graph By Day of the Week

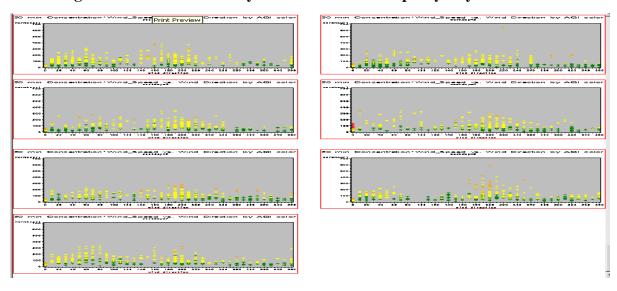


Figure F.2 Davidson County Source Location Graph By Day of the Week

Finally, correlations were computed between the TEOM concentrations for the two different TEOM sites inside Davidson County. Correlations were also examined for the three different FRM monitors inside Davidson County.

R-Value	Lexington Water	Lexington Airport	Hickory Water
P-value	Tower		Tower
Observations			
Lexington Water	1.0000	0.8918	0.6627
Tower		<.0001	<.0001
	7824	6870	6392
Lexington Airport	0.8918	1.0000	0.60617
	<.0001		<.0001
	6870	16718	15015
Hickory Water	0.6627	0.60617	1.0000
Tower	<.0001	<.0001	
	6392	15015	27727

Table G.1 Correlations between the TEOM monitors in both counties

Results and Discussion

Looking at the correlation map between all of the FRM sites in the state, a definite regional pattern can be assumed. Catawba County is highly correlated with counties that are close to it, and Davidson County shows a very strong spatial relationship from Mecklenburg County all the way up to Alamance County. This Northeast direction from Charlotte is the most heavily populated area of NC, and it is also in the predominant wind direction in the summer months.

The different days of the week were shown to be significantly different for the non-attainment sites that were being examined. There were also significant correlations between the sites inside Davidson County and Catawba County. These correlation values provide some evidence of a local component influencing the concentrations in Davidson County. Using the Federal Reference monitors, the Lexington airport site is less correlated with the Lexington water tower site than it is with both of the Hickory sites. This is also true for the Lexington Fairground site. The sites inside the town of Lexington are much closer to one another than they are to Hickory, NC. Since the FRM monitor that is used to determine attainment status is at the water tower site in Lexington, this suggests that something is happening locally at this site causing a difference in concentrations.

The TEOM data provided more observations to analyze the problem. Diurnal patterns across the state reinforced the spatial relationship. The pattern seemed to match more with a site that was closer together. By examining the plots of wind speed*concentration vs. wind direction, two sources are definite in Davidson County. One is coming from the south to southwest and the other is coming from the east. Catawba County seemed to be impacted by multiple sources.

The question of using a co-located meteorological monitor vs. a monitor that was a few miles away was answered. Two sites in Charlotte and two sites in Raleigh were examined for meteorological differences in wind speed and wind direction. Correlations were shown to be smaller than one might think for two sites that were five miles apart. Although these correlations were statistically significant it is questionable whether or not to use them in the source location analysis. This could be why the Catawba source location graph provided less useful information. Therefore it is recommended that a co-located meteorological monitor should accompany every TEOM device. It has been said that the TEOM monitors can actually have a meteorological monitor connected to it, but this has not been implemented by the state for cost reasons.

Next, plots were examined for the diurnal patterns and source locations by day of the week. In Davidson County, one abnormality can be seen. The variation at the water tower site shrinks dramatically for Saturday and Sunday. This is to be expected because usually pollution is the lowest on the weekend. At this same site the concentrations on average were lower than 15 on Saturday and Sunday. This was not the case at the airport site inside Davidson County. The variation did not shrink at all during the weekend. It stayed the same and the concentrations remained above the 15-microgram standard. In

fact, at this site the average concentrations only went below 4 times during the whole week. This clearly shows a local difference in Davidson County. The value for the variance of the weekend data was much smaller than the weekday data at the water tower site in Lexington. However, a test of significance must assume independence between samples. Examining the same graphs for Catawba County did not lead to any clues on whether their non-attainment problem is regional or local.

The source location graphs for Davidson County showed an interesting difference between the days of the week. The site that this data comes from is the site in which the variation does not shrink on the weekends. It seemed that all of the higher concentrations were coming form the south during the week, but on the weekend is when the more prominent eastern component would show up. This also helped to emphasize this local component in Davidson County. Once again the graphs for Catawba County were not as helpful or different for the different days of the week.

The correlations for the TEOM data among the different sites were very strong. Unlike the FRM monitor correlations, the TEOM correlations emphasized the regional influence showing that the sites further away were less correlated.

There are many more clues for Davidson County compared to Catawba County. A regional or spatial relationship can be shown with the FRM correlation maps. This emphasizes the regional influence. However, there are differences inside the county that could be the reason why the concentration values are high enough to call this a county a non-attainment area. Looking at the averages for the past 3 years in Mecklenburg County, which directly southwest of Davidson County, it can be shown that they are barely in attainment of the standard. This suggests that this whole area has high concentrations on a regional level, but the reason for Davidson County being over the standard is a local effect. Further analysis needs to be done on Catawba County to find an answer to their problem. As time goes by more and more data will be collected making this problem easier to understand.

ACKNOWLEDGMENTS

I would like to thank William Hunt Jr. for making all of this possible and Ben Ogorek for his help and support. I would like to thank all of the North Carolina Department of Environment and Natural Resources Air Division section. Finally, I would like to thank Bryan Stines for allowing use of his research method.

Trace Gas Monitoring for Support of the National Ambient Air Monitoring Strategy

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Abstract

In support of the National Ambient Air Monitoring Strategy (NAAMS), the EPA's Office of Air Quality, Planning and Standards (OAQPS) is testing a "new generation" of continuous gas instruments. These instruments will be used to support the monitoring of gases that are precursors to particle and ozone formation. The pollutants of interest are carbon monoxide (CO), sulfur dioxide (SO2) and reactive oxides of nitrogen (NOy). Precursor monitoring will be needed in both urban and rural areas and require that these instruments have the appropriate linear range. In addition, they will need to have better sensitivity than the standard instruments used to support the National Ambient Air Quality Standards (NAAQS). OAQPS has developed a team that is focused on developing a better understanding of these instruments, providing technical and quality assurance (QA) guidance, and providing training to monitoring agencies that are planning to implement precursor gas monitoring.

Background

The NAAMS program is "rolling out" a network that is unlike the existing State and Local Air Monitoring Stations (SLAMS) and the National Air Monitoring Stations (NAMS). This new network will be named the National Core or "NCore" network. It is designed to promote a true multiple pollutant monitoring infrastructure that will provide part of the infrastructure for future multiple pollutant based air program management. A weakness in our current monitoring infrastructure is the lack of representative inorganic gases.

In many environments, the ability to measure a "representative" concentration requires "trace gas" detection capability in the low ppb range and below, explaining the frequent reference of "trace" or "precursor" methods in the NCore program. It appears that in most urban and rural environments, trace gas capability is required for detecting ambient CO and SO2 levels. Reactive nitrogen (NOy) and nitrogen oxide (NO) require trace gas capability in rural environments and perhaps some urban locations. Some of these NCore Level 2 species (CO, SO2, and NO2) historically were used for comparisons to the NAAQS, where concentrations of interest are in the ppm range. With the exception of ozone, the remaining gaseous NAAQS are not a significant national issue. The fact that these parameters are criteria pollutants is not motivation for including these species in NCore Level 2.

Why Precursor Gas Monitoring is Needed

It is the focus of the NAMMS that certain gases be utilized for a variety of end uses: models, trends, emission control strategies and NAAQS attainment. The following are some targeted reasons for the program:

- 1. Support of advanced multiple pollutant monitoring in urban & rural areas. The NCore network will build infrastructure.
- 2. Develop emission control strategies. The precursor gas instruments will help to evaluate air quality model evaluation, rural monitoring of precursors for background transport and source apportionment and other observation-based model.
- 3. The NCore precursor gas network will support long-term health and epidemiology studies and research data uses, such as general support of atmospheric sciences.

Precursor Gas Instruments

Currently, the Precursor Gas instruments that are available are based on current technology with several modifications. The precursor CO instrument is based in Non-Dispersive Infrared (NDIR) technology that is also used for instruments that are operated for NAAQS attainment. However, in order to obtain higher sensitivity, three modifications must be made: install a high sensitivity detector, remove water vapor (interferent) and adjust the baseline frequently by directing air through a "CO scrubber" such as a heated palladium or hopcalite converter.

The Precursor SO2 instrument is very close to the higher range instrument with the following exceptions: improved organic carbon filter and high sensitivity detector. In order to improve detection, the Photomultiplier Tube is cooled.

The Precursor NOy instrument is based on the chemiluminescent NO-NOx instrument. However, there are three major differences: the molybdenum converter is external to the instrument, the baseline is automatically corrected and the instrument has a high sensitivity detector.

The Emission, Monitoring and Analysis Division of OAQPS has been testing precursor gas instrument in its Research Triangle Park, North Carolina Campus for six months. The testing facility consists of two instrument racks and all of the necessary equipment to perform the testing. To date, two CO, one SO2 and one NOy instruments have been tested. Figure 1 is an illustration of the testing facility in RTP campus. All of the instruments tested to date are commercially available from various vendors. The EPA's AMTIC website has details on how to contact the vendors.



Figure 1. OAQPS Testing Facility in Research Triangle Park, NC

The instruments were tested using National Institute of Standards and Technology (NIST) traceable standards in compressed gas cylinders and using a Mass Flow Controlled (MFC) calibration unit that allows gases and purified (zero) air to be blended accurately. The instruments were connected to analog and digital Data Acquisition Systems (DAS). The DAS collected the data during the testing for retrieval at later dates. The following list illustrates the testing performed to date:

- Averaging Time
- Concentration Range
- Lower Detection Limit

- Noise
- Linearity
- Method Detection Limit
- Zero Drift
- Span Drift
- Precision
- Bias
- Response/Lag Time
- Rise Time
- Fall Time

Technology Transfer and Training

In order to rollout the NAMMS in a timely manner, OAQPS recognized that technology transfer and training for the State/Local and Tribal agencies would be crucial to the success of the program. In late 2004, OAQPS staff was identified with the purpose of providing information critical to State, Local and Tribal agencies for implementation of the precursor monitoring network. The following are items that will be addressed in the Technology Transfer and Training:

- Background why monitoring is needed
- Presentation of individual methods and principles of operation
- Explanation of statistical evaluations
- Hardware considerations and technical issues
- Information Technology
- Data management and digital data transfer considerations
- Ouality Assurance

Timing is critical to the success of the NAMMS. For that reason, OAQPS will be having workshops in RTP, North Carolina. The workshop is under development for spring or summer 2005 and updates via newsletter, satellite broadcasts, and web-based training also under consideration.

Quality Assurance

EPA regulations state that a new monitoring program cannot be implemented with a Quality System (QS) in place. For that reason, OAQPS has been developing a QS for this program. The QS must be part of the overall QA program for all monitoring networks. The QS will, at first, begin systematic planning process and gather data for Data Quality Objectives (DQOs). This step is planned for completion Fall 2005. Once the DQOs are developed, the Data Quality Indicators will be developed to help identify the Measurement Quality Objectives (MQOs). The MQOs will, at a minimum include: precision, bias, sensitivity, completeness, comparability. Once the MQOs are developed, the QA Handbook, Volume II (Red Book) will follow. The QS system will then move into the assessment phase and will include some type of auditing program such as the National Performance Audit Program (NPAP) and Technical System Audits (TSAs).

Reference

1. EPA's National Ambient Air Monitoring Strategy (NAAMS) document (http://www.epa.gov/ttn/amtic/)

Comparison of the Proposed Versus Current Approach to Estimate Precision and Bias for Gaseous Automated Methods for the Ambient Air Monitoring Program

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Abstract

With the EPA's continuous effort to reduce pollution levels in ambient air, we are faced with new challenges to find instrumentation capable of accurately measuring lower concentrations than those needed to support standard criteria pollutant measurements. This movement towards high sensitivity monitors for precursor gas measurements within the ambient air monitoring network calls for the need to develop guidance and acceptance criteria for estimations of precision and bias for the monitors in the National Core (NCore) Network.

Important decisions are made based on criteria pollutant measurements. EPA's Office of Air Quality, Planning and Standards (OAQPS) uses the Data Quality Objective (DQO) process to ensure that any data used for these decisions are of sufficient quality. OAQPS is proposing the development of precision and bias measurement quality objectives based on confidence intervals for data aggregated by site. This proposed method minimizes the probability of making harmful, incorrect decisions by considering a conservative estimation of precision and bias at upper confidence limits.

Case studies based on precursor gas instrument testing are presented for comparison of current and proposed precision and bias measurement methods. Results show the advantage of the proposed method when used in the decision-making process.

Introduction

The National Ambient Air Monitoring Strategy (NAAMS) calls for a new network of more sensitive continuous gas instruments. This network, known as the National Core (NCore) Network, is being developed for the purpose of providing representative collocated measurements of gases and particulates. "Representative" measurements result from capturing heterogeneous mixtures of air from urban and rural locations that are relatively unaffected by nearby sources and micro-scale geographic and spatial characteristics. Instrumentation capable of detecting concentrations at the lower ppb range provides measurements that are considered to be representative. EPA's Office of Air Quality, Planning and Standards (OAQPS) is currently testing instruments capable of measuring gases at these levels. These instruments will be used to monitor gases such as carbon monoxide (CO), sulfur dioxide (SO₂) and reactive oxides of nitrogen (NO_y), which all are precursors to particle and ozone formation. Based on preliminary data from the first round of testing, important data quality indicators (DQIs), such as precision and bias, were estimated for the precursor instruments using techniques currently in CFR and more conservative techniques that are being proposed in 2005.

Conservative estimators of precision and bias minimize the probability of making harmful, incorrect decisions. Using conservative estimators also allows organizations some flexibility in the frequency of their quality control (QC) checks if they are showing results well within the acceptable range for precision and bias. Granting flexibility to eligible organizations results in a "performance-based" quality system, which provides organizations the freedom to focus their quality resources where they are most needed.

Background

The various tests run on the precursor gas instruments were range, noise, lower detectable limit, method detection limit, zero drift, span drift, lag or response time, fall time, and linearity, as well as precision and bias, which is the focus of this paper.

The test procedures for the precision and bias checks for the CO, SO₂, and NO_y monitors are as follows:

- Determine the target concentration of the precision check for each analyzer, which can be determined using analyzer sensitivity, linear range, and expected ambient concentrations
- 2. Run the precision check everyday. Record the actual concentration of the precision check and the response of the instrument*
- *Precision check consists of: (1) Running zero air through the analyzer to establish that the analyzer goes to zero (or acceptable zero), (pre-zero), (2) Collecting readings using a target concentration, (3) Averaging the concentration from these readings, and (4) Running zero gas through analyzer to flush out system (post-zero). The precision check process is illustrated in Figure 1 and Figure 2.
- 3. Calculate precision and bias using appropriate equations (40 CFR, Part 58, Appendix A, pp.225-226).

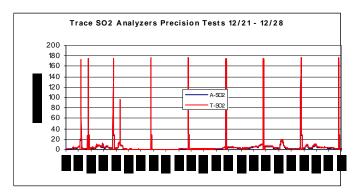


Figure 1. Graph of SO₂ Precision Testing

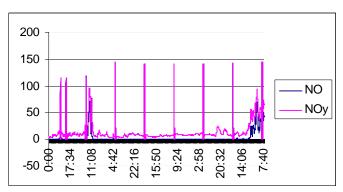


Figure 2. Graph of NO_v Precision Testing

The precursor instrument testing site is located at OAQPS' testing facility in Research Triangle Park, NC. CO, NO, and SO₂ gases are used to test two instruments from different manufacturers. NO gas was used to challenge the two channels: NO and NO_y. The sampling duration for NO testing was from 12/24/2004 to 01/05/2005 (n=13 days), using a target concentration of 19,990 ppt. For SO₂, two samplers (Sampler A and Sampler B) were tested for precision and

bias. The sampling duration for SO₂ testing was from 12/24/2004 to 01/05/2005 (n=13 days), using a target concentration of 25,500 ppt. CO testing used two samplers (Sampler A and Sampler B) to test precision and bias, however the CO had two rounds of data collection. The first round's sampling duration was from 10/08/2004 to 11/21/2004 using a target concentration of 210,000 ppt, while the second round of CO data was collected during the same period as the NO and SO₂ testing (12/24/2004 to 01/05/2005), with a target concentration of 140,000 ppt. The appended dataset, using both rounds of data, resulted in 41 observations for Sampler A and 33 observations for Sampler B. The individual datasets were used to test the hypothesis that there was no difference between the rounds of data. The F value was calculated and the variances were shown to be not significantly different. This test demonstrated the reasonableness of combining the CO data from the two testing periods.

An important issue to note is the fact that there were calibration issues during the second round of CO testing and data were adjusted to account for pre-zero and post-zero values from each sampler and test time. The calibration issues resulted from significant zero drift, which affects the instrument response at lower target concentrations. Corrections to the second round of test data were done based upon recommendations by EPA staff and are not expected to be needed in the future. The adjusted value is calculated as below:

$$Adjusted _Value = \Pr{ecision _Value} - \frac{(\Pr{e} - Zero + Post - Zero)}{2}$$

Techniques for Estimating Precision and Bias

Relative percent difference (d_i) , or individual bias of a specific instrument compared with a known value serves as the basis for the estimation of precision and bias. Variables used in this calculation are defined below:

Y₁: Indicated Value, Sampler A (or Channel A – for NO)

Y₂: Indicated Value, Sampler B (or Channel B – for NO_v)

X: Expected Value (target concentration)

Relative percent difference (d_i) is calculated below:

$$d_i = \frac{Y_i - X}{X} \cdot 100$$

where *i* represents a specific sampler or channel.

Precision is defined as the "a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation." The precision estimate, CV_{old} , for criteria pollutant QC checks using data aggregated by reporting organization, is calculated as the standard deviation, s, of the relative percent differences, d_i :

(40 CFR, Chapter 1, Part 58, Appendix A, Equation 9)

$$CV_{old} = s = \sqrt{\frac{1}{n-1} \left[\sum_{i=1}^{n} d_i^2 - \frac{1}{n} \left(\sum_{i=1}^{n} d_i \right)^2 \right]}$$

where n represents number of single point QC checks.

OAQPS proposes a precision estimator based on the upper bound of a confidence interval for the standard deviation of the relative percent differences. Using data from single point QC checks aggregated by site, CV_{new} is calculated as follows:

$$CV_{new} = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_{i}^{2} - \left(\sum_{i=1}^{n} d_{i}\right)^{2}}{(n-1) \cdot n}} \cdot \sqrt{\frac{n-1}{\chi_{0.05,(n-1)}^{2}}}$$

where $\chi^2_{0.05,(n-1)}$ is the 5th percentile of a Chi-Squared distribution with n-1 degrees of freedom.

Therefore...
$$CV_{new} = CV_{old} \cdot \sqrt{\frac{n-1}{\chi^2_{0.05,(n-1)}}}$$

Bias is defined as the "systematic or persistent distortion of a measurement process which causes errors in one direction." As stated in 40 CFR, Part 58, Appendix A, the bias estimate (*m*) for criteria pollutant QC checks using data aggregated by reporting organization, is calculated as the average of the relative percent differences (below):

$$m = \frac{1}{n} \cdot \sum_{i=1}^{n} d_i$$

OAQPS proposes using a more conservative estimator for bias based on absolute values of individual biases (relative percent differences). This new estimate is an upper bound on the mean absolute value of the relative percent differences. Like the proposed precision estimator, the bias is also calculated from the single point QC checks using data aggregated by site. The new bias (m_{new}) is calculated as:

$$m_{new} = m_{abs} + t_{\alpha,(n-1)} \cdot \frac{s_{d_abs}}{\sqrt{n}}$$

Where $t_{\alpha(n-1)}$ is the 95th quantile of a t distribution with n-1 degrees of freedom and s_{d_abs} is the standard deviation of the absolute value of the relative percent differences.

The value m_{abs} , used in the new bias estimator, is the mean of the absolute values of the relative percent differences and is calculated as:

$$m_{abs} = \frac{1}{n} \cdot \sum_{i=1}^{n} |d_i|$$

As absolute values are used to calculate bias, a positive or a negative sign can be determined based on each site's distribution of relative percent differences. Signs are only given to bias estimates with individual bias data that is significantly in the positive or negative direction. Significantly signed bias can be determined if the 25th and 75th percentiles are of the same sign (i.e. not straddling zero). For example, if both 25th and 75th percentiles were negative, the bias estimate would earn a negative sign, similarly if both percentiles were positive, a positive sign would be given to the bias estimate. A bias estimate without either sign does not have a clear bias direction with which it is associated, therefore providing an "outer-limit."

Results

The following tables and discussion reflect the preliminary results of the instrumentation testing:

The current results of the CO tests for Sampler A and Sampler B (Table 1) show that Sampler B's indicated measurements (when using target concentrations of 210,000 and 140,000 ppt) are more biased but do not appear to be significantly less precise. Sampler B's negative, "new bias," estimate is representative of a significant negative bias that is consistent with most of its readings. Sampler A's new bias estimate does not have a sign associated with it, although its "old bias" estimate is negative. The "new bias" estimate has no sign because the distribution of the instrument's individual biases about zero is not significantly negative. The "old bias" estimate is given a negative sign simply because the individual biases were averaged and the average just happened to weigh on the negative side of zero (only slightly). The sign association with the "old bias" in such a manner seems arbitrary. This example shows the merit in the new bias estimator by only associating an estimate with a sign on the condition that the direction is significant. The imprecision and large bias for the CO results could be of concern, however it is important to note that these results were using an appended dataset (from two different rounds of testing, assumed to be independent from one another) where only one round was adjusted to correct zero drift. More CO testing will be done to receive more conclusive results.

Table 1. PRECISION (%)

CO (Sampler A):		
CV OLD	CV UCL (95%) (NEW CV)	
15.2	19.0	
CO (Sampler B):		
CV OLD	CV UCL (95%) (NEW CV)	
16.5	21.2	

BIAS (%)		
CO (Sampler A):		
BIAS OLD	Absolute Bias UCL (95%) (NEW BIAS)	
-0.7	14.6	
CO (Sampler B):		
BIAS OLD	Absolute Bias UCL (95%) (NEW BIAS)	
-22.9	-27.7	

The current results of the SO₂ tests for Sampler A and Sampler B (Table 2, p.6) show that Sampler B's bias (when using a target concentration of 25,500 ppt) is almost double that of Sampler A. Sampler B's imprecision when compared to Sampler A is the same (1.5%). Sampler A and Sampler B's precision estimate of 1.5 % indicates that test readings can range anywhere from about 25,117.5 ppt to 25,882.5 ppt for a target concentration of 25,500 ppt. Neither A nor B have a signed-bias estimate, which shows that no significant bias direction could be found in the indicated readings. More SO₂ tests will be done to verify consistency in test results.

Table 2. PRECISION (%)

1 11 2 2 1 2 1 1 () 2	
SO2 (Sampler A):	
CV OLD	CV UCL (95%) (NEW CV)
0.90	1.5
SO2 (Sampler B):	
CV OLD	CV UCL (95%) (NEW CV)
1.0	1.5

DIAG (70)		
SO2 (Sampler A):		
BIAS OLD	Absolute Bias UCL (95%) (NEW BIAS)	
5.8	6.3	
SO2 (Sampler B):		
BIAS OLD	Absolute Bias UCL (95%) (NEW BIAS)	

11.3

The current results of the NO_y tests for Channel A and Channel B show no significant differences of precision and bias. Neither A nor B have a signed-bias estimate, which shows that no significant bias direction could be found in the indicated readings. More NO_y tests will be done to verify consistency in test results.

Table 3. PRECISION (%) *

NO (Channel A):	
CV OLD	CV UCL (95%) (NEW CV)
1.5	2.4
NO _y (Channel B):	
CV OLD	CV UCL (95%) (NEW CV)
1.6	2.5

BIAS (%)

RIAS (%)

10.8

NO (Channel A):	
BIAS OLD	Absolute Bias UCL (95%) (NEW BIAS)
9.5	10.3
NO _y (Channel B):	
BIAS OLD	Absolute Bias UCL (95%) (BIAS NEW)
10.3	11.1

^{*} Precision is estimated using NO calibration gas

Current versus Proposed Precision and Bias Estimation in the Real World

The emphasis on conservative estimators at upper limits represents "worst-case scenario," but how is it advantageous in the "real-world?" As these instruments monitor gases which are precursors to particle and ozone formation, understanding uncertainty within the measured concentrations is very important from both a human health and an environmental quality perspective. *Underestimating* an instrument's uncertainty can result in undetected calibration problems within the monitoring network, as well as cause higher unknown human exposure risk. Identifying problems with a monitor more quickly results in the instrument being serviced sooner, therefore improving the quality of monitoring data. Considering conservative estimators of precision and bias minimizes undetected monitor problems as well as unknown risk exposure by reducing the chances of underestimating a monitor's uncertainty. Monte Carlo simulations can be run using each criteria pollutant's "real-world" estimated precision and bias range to simulate the actual precision and bias of monitors in the field. Simulations were run for this purpose using SAS. The results from these simulations were used to compare the probability of underestimating uncertainty using both current and proposed statistical techniques.

The precision upper bound estimates in 2003 for non-precursor gases: CO, SO₂, and NO₂, were 3.51%, 3.62%, and 4.88%, respectively ². Precision simulations were run using a precision of 2, 3, 4, and 5% (to cover all possibilities of CO, SO₂, and NO₂ precision in the field). Results show that out of 10,000 runs (trials) for each set precision parameter, the actual precision of the

monitor was underestimated approximately 55% of the time using the old precision estimate, and was underestimated approximately 3.7% of the time using the new precision estimate.

The bias upper bound estimates in 2003 for CO, SO₂, and NO₂ were 2.04%, 3.34%, 4.43%, respectively.² Bias simulations were run using a bias of 1 to 10% (to cover all possibilities of CO, SO₂, and NO₂ bias in the field) assuming a realistic, constant precision depending on gaseous pollutant. The chances of underestimating bias using the old bias estimator stayed constant at around 50% regardless of bias input value. The chances of underestimating bias using the new bias estimator increased from 0% to 5% (when using an input of bias of 1, 2, 3, and 4%), but stabilized at around 5% for an input of 5% bias and above. Results show that out of 10,000 runs (trials) for each set bias parameter (assuming constant precision), the actual bias of the monitor was underestimated approximately 50% of the time using the old bias estimate, and was underestimated approximately 5% of the time using the new bias estimate.

The results from the Monte Carlo simulations are consistent with the theory behind upper confidence limits and show the advantage of using more conservative estimators of precision and bias over the methods currently in CFR.

References

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Introduction to the IMPROVE program's new interactive web-based data validation tools Linsey DeBell, Nicole Hyslop, Lowell Ashbaugh, Bret Schichtel, Chuck McDade, Bill Malm, Marc Pitchford, Doug Fox

Abstract:

The Interagency Monitoring of Protected Visual Environments (IMPROVE) program is developing new web-based tools to augment the current data validation process. The new application utilizes interactive data selection from the Visibility Information Exchange Web System (VIEWS) database, on-the-fly calculation of diagnostic statistics and/or composite parameters, and on-line charting capabilities. The tools will allow the user to produce the data validation charts used by both the Crocker Nuclear Laboratory (CNL) at University of California Davis and the Cooperative Institute for Research in the Atmosphere (CIRA) at Colorado State University. The user is able to customize the charts through selecting start and end dates, site(s) or IMPROVE regions, and chart type.

1. Introduction

The Interagency Monitoring of Protected Visual Environments (IMPROVE) program is a cooperative measurement effort designed to identify chemical species and emission sources responsible for existing man-made visibility impairment and to document long-term trends for assessing progress towards the national visibility goal. With the enactment of the Regional Haze Rule, an additional goal has become to establish current visibility and aerosol conditions in mandatory visibility protected federal areas (VPFAs). In order to meet these objectives, the program has the responsibility for ensuring that a dataset of suitable quality for scientific inquiry and for regulatory use is gathered, analyzed and made available to the stakeholders.

The primary goal for IMPROVE under the new Regional Haze Rule Guidelines for Tracking Progress is to be able to make a valid comparison between consecutive five-year averages of the 20% worst and 20% best visibility days. The IMPROVE program is in the process of reviewing and refining our Data Quality Objective (DQO) to ensure that it is consistent with these new guidelines. As part of that review process, all the Measurement Quality Objectives (MQOs) are also being reviewed and may be revised as necessary. The MQOs include measurement specific objectives in precision, accuracy, minimum quantifiable limit (MQL), data completeness, data representativeness, and data comparability. Secondary objectives of the IMPROVE program, including measurement of trace elements for source apportionment, will also be taken into account when reviewing the MQOs.

To meet this goal, IMPROVE maintains a continually developing quality assurance (QA) program to ensure that the data quality objectives of the Regional Haze Rule are met or exceeded. The data validation system is a key component of this program. The role of this system is to verify that the MQOs of the program are met for each and every data point and that appropriate actions, such as flagging the data, are taken when the MQOs cannot be met. The task

of performing data validation is shared amongst several organizations including the Crocker Nuclear Laboratory (CNL) at University of California Davis and the Cooperative Institute for Research in the Atmosphere (CIRA) at Colorado State University, the Desert Research Institute (DRI) at the University of Nevada and the Research Triangle Institute (RTI).

The validation system is inextricably linked to the data management and quality control systems. The data management system controls the flow of data from the sampler to the final database, the validation system ensures that proper decisions are made along the way and the quality control system informs the decision making process. Efforts to better integrate these systems are currently underway. One component of this process is the development of new web-based tools to augment the current data validation process. The new application utilizes interactive data selection from the Visibility Information Exchange Web System (VIEWS) database (http://vista.cira.colostate.edu/views/), on-the-fly calculation of diagnostic statistics and/or composite parameters, and on-line charting capabilities.

The full data validation system spans a wide scope of tests from low level checks on sample identity to high level checks on temporal comparability. The new tools currently only incorporate the higher level data validation tests which have been used historically in the IMPROVE program. However, they are being expanded to include tests that were too cumbersome and resource intensive to implement in the past. New tests will be continually added as needed to address issues that are identified as part of our on-going quality control program and as additional supporting datasets are incorporated into the database. Both the new tools and the underlying data validation theory will be described in detail in the sections that follow.

2. Data Validation Theory

The IMPROVE system has been designed to include internal measurement redundancy, a valuable asset for data validation. Examples include Fe from both XRF systems, SO_4^- and S from two independent sampling trains, and various modeled relationships which allows for the inter-comparison of results from the four independent modules (see section 2.3 for more detail). An additional asset to the validation system is the calculation and reporting of uncertainty and MDL for every data point. The uncertainty is used to calculate a t-statistic in comparing values such as sulfur and sulfate to determine how far apart they are relative to their uncertainties (see section 2.3). This provides a quantitative alert to values that may be statistically distinct from each other. The MDL is provided for data analysts to use as a basis for evaluating the robustness of measured values.

The data validation checks have been designed to assess the following: that uncertainty, accuracy and MQL objectives are being met; that there is internal consistency between the redundant measurements; that spatial and temporal comparability are being maintained; and that there is external consistency between the aerosol chemical and physical measurements and the optical measurements.

The IMPROVE program defines four levels of data validation:

Table 2. Data Validation Levels

Level 0 (Performed by field and lab staff)	Level 1 (Performed by QA personnel at
Sample Identification	CNL)
Operator Observations	 Mass balance
Sampler Flags	 Field Operations Database Review
Shipping & Disassembly	 Lab Operations Database Review
• Laboratory Checks (per SOPs)	 Flow Rate Analysis
Range Checking	 Flagged Samples Review
• Flow Rate audits	 QC samples and analytical accuracy
• Exposure Duration checks	and precision review
Elapsed time before retrieval	
Holding times	
Level 2 (Performed by QA personnel at	Level 3 (Performed by QA personnel at
CNL)	CIRA)
• Internal Consistency Analysis	• Time Series Analysis
Outlier Analysis	 Correlations between sites
Data Completeness	 Mass Reconstruction Analysis
 Collocated Bias and Precision 	 Species Distribution Analysis
	 Optical Reconstruction Analysis
	• Others
	Modeling

CNL performs level 0 through level 2 validations on every batch of data both during the analysis process and after all four modules have been analyzed. RTI and DRI also conduct various level 0 checks on all data they submit to CNL. Any inconsistencies or other problems identified in this review are corrected prior to sending the data to CIRA. CIRA performs additional level 3 validation tests on all data on either a quarterly or annual basis.

2.1 Data Integrity Checks

Data integrity checks are performed after every data transfer and transformation process to ensure that all data are accurately appended to the final database and made available to the public by CIRA. Most tests are SQL based and performed during or just after the data ingest process. Examples include testing the final submitted dataset from the labs for

- The presence of internal QA flags,
- The presence of unknown QA flags,
- Proper application of QA flags,
- The presence of unknown sites,
- The presence of unknown parameters,
- Record completeness (e.g. value, mdl and uncertainty for every parameter),
- The presence of duplicate primary keys,
- Successful transformation to a fully normalized schema without data loss or errors, and

• Data delivery completeness.

2.2 Accuracy, Uncertainty and MQL Checks on QC Samples

All calibration standards for XRF, IC and TOR are NIST traceable. Calibrations are performed prior to analyzing every batch of samples. Adjustments are made to the systems until they are in agreement with the known standards within a tolerable range for meeting the MQOs for accuracy.

Flow rate accuracy is a critical aspect of overall system accuracy. Internal and external flow rate audits ensure that the sampling system is kept within tolerable limits for meeting the MQOs. Acceptance criteria on the monitored flow rates also ensure that each sample is representative of $PM_{2.5}$ aerosol to within the stated tolerable limits.

Replicate samples are run as part of every batch to ensure that the system precision remains within tolerable limits for meeting the MQOs. A further test on the precision of the overall sampling and analytical system is collocated samplers. The observed differences in collocated data are directly comparable to the MQOs. Also, the observed differences in collocated data are compared to the estimated uncertainties reported with each data value to determine if the reported values are accurate.

New data validation tests to ensure MQO conformance will likely be developed as part of the MQO review and revision process.

2.3 Internal Consistency Checks on all Samples

- Fe·Fe
 - Both x-ray systems are equally sensitive for iron, and comparisons of the iron measurements by both systems is a routine part of quality assurance.
- PM₁₀:PM_{2.5} Every sample in the batch is analyzed to see if PM₁₀-PM_{2.5}≥0, within measurement uncertainty, both at the time of weighing and after all modules have been analyzed.
- SO₄=:3*S Every sample in the batch is analyzed to see if (SO₄=)-(3*S) =0 within measurement uncertainty after all modules have been analyzed.
- RCFM:MF
 - Every sample in the batch is analyzed to see if RCFM-MF=0 within measurement and model uncertainty after all modules have been analyzed. Currently this test is based on the judgment of the QA manager. Efforts to better quantify the uncertainty in the RCFM model and the expected agreement between the modeled and measured PM_{2.5} mass are underway.
- OMH:OMC
 - The dataset is analyzed to see if OMH is in agreement with OMC within expectations after all modules have been analyzed. Currently this test is based on the judgment of the QA manager. Efforts to better quantify the uncertainty in the OMH and OMC models

and the expected agreement between the two models of organic carbon mass are underway.

2.4 Spatial and Temporal Comparability Checks on all Samples

Maintaining comparability across the network in both space and time is crucial. Time series analyses of the composite variables included in the Regional Haze Rule calculations are conducted to monitor changes that may be related to the data collection and processing rather than a true representation of ambient conditions. Spatial analysis is limited in scope and incorporated into other data validation checks.

Implementing these checks is currently a qualitative process performed semi-annually by CIRA with the participation of key individuals from CNL and NPS. The outcomes of past checks of this type have included special studies, some still in progress, to understand data inconsistencies for identified issues as well as changes in data collection and data management practices and procedures. When a potential issue with the data is identified, a QA/QC issue report is written identifying for users the potential problem and recommendation for handling the problem in any data analysis. These reports are available from the IMPROVE website at: http://vista.cira.colostate.edu/improve/Data/QA_QC/issues.htm.

2.5 External Consistency Checks on all Samples

The IMPROVE network also measures optical properties, including aerosol scattering and light extinction, at a number of sites. On a periodic basis at CIRA, temporal and regression analyses of reconstructed versus observed optical properties will be performed for those sites where both datasets are available. By interfacing the aerosol and optical data, the consistency of the two disparate datasets can be compared and the algorithms for relating aerosol with optical effects can be evaluated regularly.

3. New Data Validation Tools

The new data validation web application utilizes interactive data selection from the Visibility Information Exchange Web System (VIEWS) database (http://vista.cira.colostate.edu/views/), on-the-fly calculation of diagnostic statistics and/or composite parameters, and on-line charting capabilities. The tools are being built as ASP .NET web pages in Microsoft Visual Studio .NET. The web application integrates the third party data display and analysis package Chart FX with the SQL Server database utilizing Visual Basic and ADO .NET to access the database. The user is able to produce the high level data validation charts used by IMPROVE. Charts are customized through selecting start and end dates, site(s) or IMPROVE regions, and chart type.

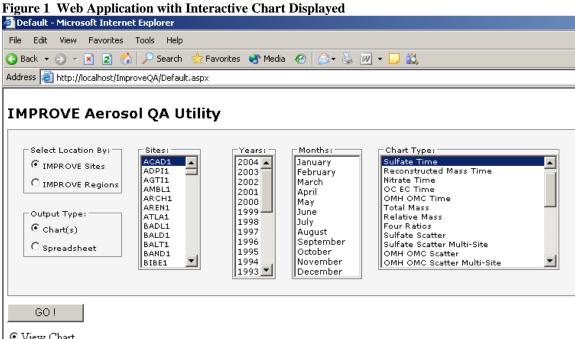
User selections are used to dynamically build SQL queries which are used to retrieve the necessary data for the specified site, time and chart type. Filtering of the data based on QA flag, concentration, state or any other data or metadata parameter stored in the relational database can be handled either at the data retrieval stage or at the in-memory data processing stage. Only the necessary raw data (parameter value, mdl and unc) and metadata is retrieved from the database,

all composite parameters and statistics are calculated using IMPROVE algorithms and added to the in-memory dataset object. The in-memory dataset is formatted and processed for producing Chart FX chart objects which can be displayed as interactive charts on the web page or saved directly to the user's hard drive. The user can also choose to view the data in a table on the web page rather than as a chart.

The application currently includes the ability to generate scatter charts and multi-panel time series charts. The available chart types are designed for looking at the internal consistency between redundant measurements and comparing measured parameters to various models. Specific examples include scatter charts of reconstructed PM_{2.5} (RCFM) versus measured PM_{2.5} mass, sulfate (SO₄) versus 3*Sulfur (S), and organic mass by hydrogen versus organic mass by carbon, and time series charts of SO₄, S and the ratio SO₄/S, and OC, EC and OC/EC (Figure 1 and 2). The charts, where appropriate, include visual identification of data points below mdl. Charts displayed on the web page include scalable axes and mouse over and data grid capabilities for viewing individual data point values (Figure 1.).

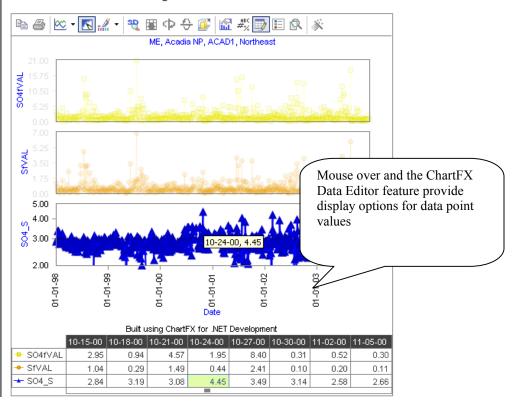
Additional tools available through the VIEWS system, such as the site browser and query wizard, greatly aid in the data validation process as they offer easy access to site and network metadata for investigating anomalous behavior apparent in data validation charts. Examples of the metadata available through these tools include site location including maps, site description including photos, and network history notes including dates of major sampling or analytical switches.





View Chart

C Download chart without viewing



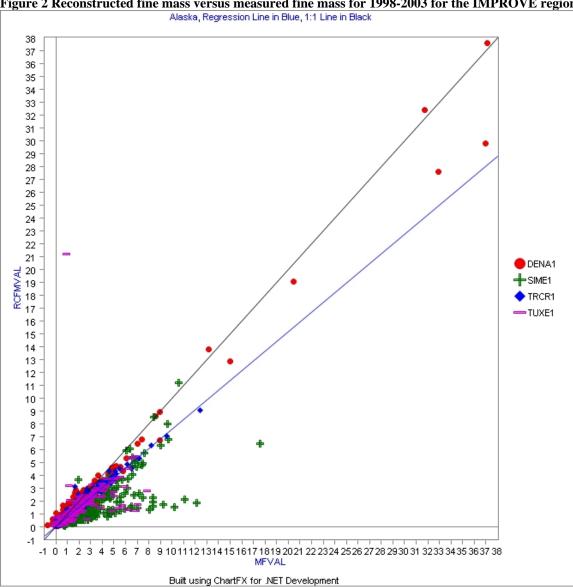


Figure 2 Reconstructed fine mass versus measured fine mass for 1998-2003 for the IMPROVE region Alaska

4. Conclusions

All final QA/QC tools and results will be publicly available via the IMPROVE website: http://vista.cira.colostate.edu/improve/. These web-based tools will allow all interested parties to implement the same internal consistency, comparability and external consistency tests that CIRA and CNL conduct. These tools, along with the annual quality assurance report, will allow all data users and stakeholders in the IMPROVE program to verify the results of the data validation process.

The role of QA in determination of effects of shipping procedures for PM2.5 speciation filters

The PM2.5 chemical speciation program spends nearly \$1.8 MM per year on shipping of filter modules between the analytical service laboratory and the sampling site or site operator's staging facility. The high cost is due a requirement that samples be kept refrigerated from the time they are removed from the sampler to the time of their analysis, which dictates a sizable and weighty shipping container. The samples are shipped via overnight contract carrier. There are those in the science community who argue that cold shipping is unnecessary. An ad hoc group composed of EPA scientists, State monitoring technicians, and supporting contractors devised a field study to examine the differential effects of using a plastic corrugated box with expanded foam padding, shipped at the three-day economy rate. The study was originally designed to occur at two or three locations with differing dominant pollutants in the local PM2.5 aerosols. The study plan was to sample on an intensive 4-day-per-week, but to skip days that were biased by heavy rain, i.e., air pollution would be scrubbed from the air. Our goal was to collect data for 30 sampling events that were likely to produce valid data points. This paper will describe some of the challenges we encountered, lessons we learned, and resulting new directions in trying to make such an assessment. The amount of data from just one sampling location is massive. Some of the preliminary data from the first sampling location of the study, Atlanta, will be reviewed. We'll discuss our approach to assessing the quality of the data and interpreting the data.

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(others to be listed)